

# The role of Parent Perception of Burden on Child Health Related Quality of Life: Examining Functioning among Children with Food Allergy

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by

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### Abstract

Recently rates of Food Allergies (FA) in children have been increasing in prevalence. International research has shown FA is associated with impaired Health-Related Quality of Life (HRQoL) as well as increased anxiety in both children and parents of children with FA. This was the first study to examine FA-specific factors with psychological variables in New Zealand children with FA. The aim of the study was to examine the relationship between FA severity and child HRQoL, as well as to investigate moderating variables, such as parent anxiety and parental burden associated with FA and child HRQoL. The sample consisted of 154 children with FA and their caregivers, recruited through social media and email newsletters. Caregivers completed questionnaires assessing demographics, FA characteristics, child and parent measures of anxiety, child reported and parent reported child HRQoL, and disease burden.

It was hypothesised that (1) children with FA would report lower levels of HRQoL compared to healthy controls (2) children with multiple FA would report poorer HRQoL compared to children with one or two FA's (3) FA severity would be associated with low levels of child HRQoL (4) primary caregiver's anxiety would moderate the relationship between FA and HRQoL (5) primary caregiver's sense of perceived burden would moderate the relationship between FA and HRQoL.

Results indicated that (1) children with FA exhibited significantly *poorer* HRQoL compared to healthy children; (2) children with multiple allergies did not report significantly poorer HRQoL compared to children with one or two FA's; (3) higher FA severity predicted *poorer* child HRQoL as reported by parents but not children; (4) the association between FA severity and child HRQoL was not moderated by caregiver anxiety; and (5) the association between FA severity and HRQoL was not moderated by parent burden. These findings suggest that children with FA and their caregivers in New Zealand should be considered vulnerable to increased anxiety, especially if the child has a severe

FA. Finally, these findings may help inform future clinical efforts that are specifically designed to reduce caregiver sense of burden, as well as caregiver stress and anxiety, among families with FA.

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## **Introduction**

Food Allergy (FA) is an adverse, abnormal reaction to food proteins stemming from the immune system (Allen, Hill, & Heine, 2006; Knibb & Stalker, 2013) with a range of symptoms that can affect the cardiovascular, respiratory, skin, and digestive systems. These symptoms can be mild (e.g., itchiness) or they can be extremely severe, as with anaphylaxis, which requires a life-saving injection of adrenaline. Current estimates of FA worldwide suggest a prevalence rate of approximately 6-7% of children (Boyle et al., 2017). Although gaining accurate prevalence rates from research is challenging, due to lack of objectively assessed reliable data, FA rates appear to be increasing in Western countries such as the United Kingdom, Australia, and the United States (Sicherer & Sampson, 2018; Tang & Mullins, 2017). It is thought that rates will continue to steadily rise in developing countries as they start to adopt a more Westernised lifestyle due to evidence that children from areas such as East Asia have increased risk of developing FA when exposed to Western diets than do Caucasian children (Tang & Mullins, 2017). The increasing prevalence is particularly noticeable in older children and adolescents, which is concerning given that the rate of fatalities from FA reactions are highest in this age group (Bock, Muñoz-Furlong, & Sampson, 2007). It is thought that these prevalence rates will continue to rise globally over the short to medium term until a cure for FA or effective treatment is discovered (Tang & Mullins, 2017). Presently, there are no reliable prevalence statistics for childhood FA in New Zealand (Crooks et al, 2008).

It is not difficult to imagine the economic impact FA can have, when one considers both the prevalence of the illness and the time families spend managing it. Although there are no estimates of medical costs related to FA in New Zealand, preventing and treating FA in children costs nearly 25 billion dollars a year in the United States alone, with almost 40% of the paediatric population

presenting with FA having experienced a life-threatening reaction (Bilaver, Kester, Smith & Gupta, 2016; Gupta et al., 2013). The majority of these costs are borne by the families and include lost labour, due to needing to take time off work to care for these children, and out-of-pocket expenses for specialty foods (Gupta et al., 2013). A recent study by Protudjer and colleagues (2015) indicated that both direct (e.g., medications) and indirect (e.g., time spent at medical appointments, shopping, etc.) household costs associated with FA, were approximately 4000 Euro higher in FA households with children and 4800 Euro higher in FA households with adolescents among Swedish families.

To gain a better understanding of the aforementioned findings related to the time families with FA spend on illness related issues, it is important to examine the treatment of FA. Although there has been some success with specific treatment methods, such as oral immunotherapy (Bégin et al., 2014), which aim to create desensitisation, these therapies are currently mostly available only in research settings and a select few private practices of board-certified allergists. To date, there are no options for oral immunotherapy to food in New Zealand, and the safety and efficacy of these particular treatment options are still being established (Sampath, Sindher, Zhang & Nadeau, 2018). Further, the specific features of the therapy, such as the length of time the children treated need to keep consuming a maintenance daily dose to prevent sensitisation returning, are also still being established (Sicherer & Sampson, 2017). Although the number of ongoing studies examining a range of therapies is exciting, at present there is no publicly available cure for FA recommended by the major allergy organisations such as the National Institute of Allergy and Infectious Diseases (Boyce et al, 2011). Thus, management involves strict avoidance of the allergen, constant vigilance and rapid treatment when an allergic reaction occurs, all of which require a high level of education and vigilance for the patient and the caregiver (Sicherer & Sampson, 2017). This can be difficult, since common allergens such as milk and egg are found in many commercial food products. Successful avoidance involves efforts from both the child with FA and their parents, but also includes trust in the wider community (e.g., the school, friends, the entire family unit), which is necessary for keeping them safe (Sicherer &

Sampson, 2017). The problem of strict avoidance is compounded, as there is a large variation in clear labeling of these products, which requires constant ingredient checking by children, adolescents, and caregivers. As one might assume, this constant vigilance has been found to affect the wellbeing of the child with FA and their families (Bollinger et al., 2006).

### *Parental burden in families with food allergy*

As one can imagine, parents of children with FA report a high sense of burden related to looking after their children (Bollinger et al., 2006). Within the context of FA, burden refers to a range of different domains and emotional issues related to caring for a child with FA. Specifically, burden captures the difficulties of family/social activities (e.g. school activities, eating at restaurants, attending parties), leaving children in the care of others, letting children sit near others while eating, the time required for meal preparation, health and nutritional concerns, fear about their ability to help in the case of a future allergic reaction, and sadness and worry about their child's future (Cohen, Noone, Muñoz-Furlong & Sicherer, 2004). Nearly half of parents in a recent study investigating FA-related burden reported moderate to severe limitations in caring for their family, such as planning social activities, eating out, and entrusting their children's care to others (Allen, Bidarkar, vanNunen & Campbell, 2015).

One of the primary factors shown to affect parental burden includes the number of allergies a child has (Allen et al., 2015). In fact, the relationship between the number of FAs and parent-perceived burden is stronger than needing to carry an adrenaline auto-injector (a.k.a., EpiPen) constantly, which is another factor known to increase the burden within families with FA (Allen et al., 2015). These findings become particularly concerning when one considers the impact this burden can have on the daily lives of children with FA and their families.

Specifically, research has shown that FA has a significant impact on the day-to-day lives of families, affecting family social activities, meal preparation, school attendance, and family stress levels (Allen et al., 2015; Bollinger et al., 2006; Cohen et al., 2004). Further, studies have shown that

approximately 10% of families with a child who has an FA, choose to home school their children due to their concerns about keeping them safe from allergens (Bollinger, 2016). Parents also admit avoiding school camps, school outings, sending children to preschool or day-care, going to restaurants, letting their children go to friend's houses for play dates, camps, and sleepovers (Bollinger et al., 2016). Valentine and Knibb (2011) found that the burden of responsibility for caring for children with FA impacted on parents much more than children. In a similar study, Springston and colleagues (2010) found a wide variation in scores on the Food Allergy Quality of Life-Parental burden scale (FAQL-PB; Cohen, Noone, Muñoz-Furlong, & Sicherer, 2004), a measure designed to evaluate the impact FA has on a child's quality of life, with nearly all participants at least moderately troubled by social interactions and limitations. These authors also found that parental burden was higher for parents of children with multiple allergies, with approximately 65% of the sample reporting moderate or extreme discontent with the extra time required to prepare safe meals for their child with FA.

### *Health-Related Quality of Life*

In addition to the aforementioned problems the families of children with FA can face, FA can impact the lives of the child in many other ways, particularly their HRQoL. HRQoL can be described as an individual's perception of the influence of health status on physical, psychological, and social functioning, which is multidimensional and subjective in nature and has become a popular outcome measure for helping researchers and clinicians understand the impact illness can have on a child or adolescent (Matza, Swensen, Flood, Secnik, & Leidy, 2004). Because children exist in unique contexts (e.g., family, school, peers), which can mediate the impact of chronic disease on well-being, child measures of HRQoL must take these factors into account. That is, HRQoL measures are important, as they are able to examine a broad range of outcomes and measure the impact of chronic disease on overall functioning, rather than exclusively capturing clinical indicators of health (e.g., itching, hives, wheezing). Ideally, this is able to help provide more effective treatments for children with chronic health conditions (Matza et al., 2004), as this allows us to understand the effect FA is



having on the “whole child.” It is intuitive that both adults and children with FA report significantly lower levels of HRQoL than their healthy counterparts (Primeau et al., 2000; Valentine & Knibb, 2011) and children without FA (King, Knibb & Hourihane, 2009).

### *Anxiety*

Although the majority of families with FA adapt to their child’s condition over time, and report normal levels of anxiety, some families experience an exacerbation of these symptoms upon and after diagnosis of their child’s FA (Zijlstra et al., 2010). It has been suggested that the constant vigilance required to look after children with FA can significantly increase anxiety (Warren, Otto, Walkner & Gupta, 2016). This seems to be supported by findings showing that anxiety is a commonly reported problem in parents of children with FA, especially mothers (Lau et al., 2014), and the severity of this anxiety has been shown to subsequently impact their child’s HRQoL (Chow, Pincus & Comer, 2015). This can be a difficult dilemma for parents, as a certain level of hypervigilance is appropriate when parenting children with FAs, especially those with a history of anaphylaxis. For example, Mandell and colleagues (2005) reported that most families with a child with FA follow a similar pattern of anxiety, where the high anxiety levels immediately following their child’s diagnosis acts to motivate families to seek out information, support and guidance from different agencies and clinical resources. Further results indicate that this was then often followed by a rapid decrease in anxiety once the family had established their specific coping strategies. The authors reported that factors such as a new serious allergic reaction acted to increase anxiety again and necessitated a repeat of the aforementioned cycle. However, in contrast to some families with maladaptive levels of very high anxiety over time, the authors indicated that some families with very low levels of anxiety often failed to keep up adequate levels of vigilance that act to keep children safe. Again, families face a very real dilemma as they are forced to find the optimal balance between vigilance and risk (Warren, Otto, Walkner & Gupta, 2016), which will obviously differ from family to family due to certain factors (e.g., FA type, FA severity, etc.).

It has been hypothesised that families of children with nut allergies may experience high stress due to the serious, and often life-threatening, reactions children with these allergies experience (Clark & Ewan, 2003; Cummings et al., 2010). In a study of children with suspected peanut and hazelnut allergies undergoing double-blind placebo-controlled food challenges, Zijlstra and colleagues (2010) found both mothers and fathers had very high levels of anxiety just prior to the challenge. In fact, their anxiety levels were comparable to those for individuals with test anxiety, women undergoing in vitro fertilisation, and pregnant women who had previously lost a child to Sudden Infant Death Syndrome (SIDS). In similar studies, parents have reported constant, overwhelming worry, and paralysing fear resulting in a sense of daily struggle (Cummings et al., 2010). For example, Springston and colleagues (2010) found that among a sample of over 1000 caregivers of children with FA, 26% reported having extreme anxiety related to their child's FA and a similar proportion said they felt extremely troubled by sadness about the burden related to their child's FA. A similar line of research suggests that parents of children with FA may be passing on their own negative feelings and anxiety to their child, which may be evidenced by the findings that there was a significant mismatch between their child's own food allergy-related anxiety and their actual clinical history of reactions (DunnGalvin, Gaffney & Hourihane, 2009).

#### *Other Factors to Consider*

Perhaps one of the more obvious factors that can increase the impact FA has on the well-being of a family, is the number and severity of the child's FAs. This can be seen as an especially alarming idea when one considers how a review of the literature indicates many children with FA have multiple allergies (King et al., 2009). Specifically, Springston and colleagues (2010) found more than three quarters of their large sample of more than 1000 caregivers of children with FA had multiple allergies with nearly half of this sample having experienced anaphylaxis. Additionally, while developing the FAQL-PB scale, a measure of parent-perceived burden for their child's FA, Cohen and colleagues (2004) found just slightly more than half the sample had one or two allergies, and just under half had

three or more allergies. Researchers have indeed investigated whether the experience of dealing with multiple allergies has an impact on the aforementioned variables such as HRQoL and anxiety. For example, LeBovidge and colleagues (2009) found that having multiple allergies predicted parental anxiety, distress, and other psychosocial variables, more so than for families with a single allergy. Despite the aforementioned studies, more research is warranted to gain a better understanding of these phenomena. Specifically, there is currently a gap in the literature regarding the prevalence, form and seriousness of FA in children residing in New Zealand, and a lack of research investigating the psychological effect these FAs have on their primary caregiver.

### *Summary*

In summary, currently the only recommended way to manage FA is to strictly avoid the allergen, which is a formidable task and places the weight of avoiding potentially fatal reactions squarely on the shoulders of children, adolescents, and/or their caregivers. It is clear that this required vigilance can leave parents feeling a great sense of burden. The studies detailed above have revealed increased anxiety levels in these families with FA, particularly in mothers. Furthermore, HRQoL is clearly affected in children with FA; however, the mechanisms by which this happens are less clear. More specifically, the factors that may moderate the relationship between FA and a child or adolescent's HRQoL are unclear. Factors related to FA have been shown to be associated with decreased HRQoL and parental burden, such as evidence of multiple FAs and needing to carry adrenaline auto-injectors at all times. Given the findings within the literature to date, and the lack of research conducted among the population within New Zealand, it can be seen as an important next step to develop a better understanding of the mechanisms that impact children's functioning both positively and negatively. Therefore, this study aims to identify specific moderators of the relationships between FA illness severity and child HRQoL. Ultimately, this knowledge may inform tailored programmes that are designed to improve the HRQoL of children and families with FA by identifying areas for targeted intervention efforts. Additionally, this study will provide a unique

contribution to the literature by generating empirical data on the prevalence of FA in NZ, which is significantly lacking to date.

## Literature Review

Internationally, rates of chronic health conditions in paediatric populations have been increasing steadily over the last five decades (Van Cleave, Gortmaker & Perrin, 2010) with approximately 18% of New Zealand youth experiencing at least one chronic health condition which has been associated with increased rates of emotional distress (Denny et al., 2014). Chronic health conditions in children are seldom completely cured and many are shown to be increasing in prevalence in recent times (Van Der Lee, Mookink, Grootenhuis, Heymans & Offringa, 2007). FA is one of the most common chronic diseases seen in children with rapidly increasing prevalence rates internationally (Sicherer & Sampson, 2018), yet FA is still poorly understood in terms of underlying causes, management and treatment (Burks et al., 2012; Sampson, 2004; Sicherer, 2002).

### *What is Food Allergy?*

Symptoms of FA, an adverse reaction to food stemming from the immune system (Knibb and Stalker, 2013), can be seen in a number of organs: the skin (e.g., urticaria, flushing, dermatitis), the gastrointestinal tract (e.g., vomiting, abdominal cramping, swelling of the tongue), the respiratory tract (e.g., sneezing, nasal congestion, wheezing, repetitive cough), and the cardiovascular system, (e.g., dizziness, hypotension and shock). Research has also shown that cramping pain in the back and having a sense of ‘impending doom’ may also be present (Sampson, 1999). The most severe reaction to FA, however, is anaphylaxis: a multi system reaction that can come on extremely quickly and lead to loss of life. Food is the leading cause of anaphylaxis in children and is avoidable only by strict vigilance of the allergen. Following exposure to the allergen, the respiratory system may be compromised, with shock and cardiovascular collapse in severe cases or when treatment is delayed (Akeson, Worth & Sheikh, 2007). Unfortunately, to date, there is not a universally accepted definition of anaphylaxis, which can be confusing to those working in the medical field, and families dealing

with severe FA (Akeson et al., 2007). Most severe allergic reactions are attributable to IgE-mediated allergy, just one form of food hypersensitivity (Sampson et al., 2006), which requires immediate administration of epinephrine typically via an adrenaline auto-injector (AAI), such as an EpiPen (Sampson, 2006).

Although IgE-mediated allergic conditions are responsible for the most severe of reactions in children, non-IgE-mediated disorders (e.g., eosinophilic gastroenteritis, dietary protein-induced enterocolitis) have been shown to adversely affect children's well-being with symptoms such as vomiting, dysphagia and pain (Klinnert et al., 2015). For these types of disorders, biopsy samples may be used to confirm this diagnosis, but individual foods that may be causing the disorder are, as yet, unable to be identified (Sampson, 1999). Another food associated disorder affecting children is Coeliac Disease (CD), an autoimmune-mediated condition related to sensitivity to a component of gluten, which is found in wheat, rye, and barley. Symptoms include abdominal pain, chronic vomiting and diarrhoea and are triggered by exposure to gluten in the diet. Following a diagnosis of CD, it is necessary to carefully eliminate all foods containing gluten, which can be an incredibly difficult challenge that requires significant changes to a child's diet and if not done carefully can lead to chronic inflammation and tissue damage (Sampson, 2003).

### *Diagnosis of Food Allergy*

Usually FA diagnosis is performed by an allergist who evaluates a patient's medical history, which informs their judgement about whether the problems are likely caused by immunologic mechanisms, and therefore either IgE-mediated or non-IgE-mediated. This typically results in further testing (e.g., skin prick tests, blood tests) and oral challenges to verify the allergy. Ultimately, the allergy diagnostic gold standard is considered to be a double-blind placebo-controlled food challenge (DBPCFC). These challenges consist of a food challenge tailored to an individual's age, previous reactions and test history, and are performed in a hospital or clinic setting with specialist medical staff trained in recognising symptoms and signs of an allergic reaction who are able to provide life-saving

intervention quickly and efficiently (Nowak-Węgrzyn et al., 2009). Common testing, such as skin prick tests are notorious for having limited predictive accuracy compared to DBPCFCs, therefore a positive result on these tests does not actually confirm FA, but merely shows a possible positive association between reactivity and the allergen.

### *Food Allergy Prevalence Rates*

Obtaining accurate international prevalence rates is difficult, given the incredible idiosyncrasies of FA. Over half of all countries worldwide had no available prevalence rates in a global survey of FA (Prescott et al, 2013), with only 10% of a sample of 89 countries having ideal prevalence rates obtained by the gold standard of FA diagnosis (i.e., DBPCFC). Countries who presented data on prevalence showed rates ranging between 1% (Thailand) and 10% (Australia). For example, the United Kingdom has a prevalence rate of 4% (Prescott et al., 2013). Current estimates of FA worldwide suggest a prevalence rate of approximately 6-7% of children (Boyle et al., 2017) with unknown prevalence in ethnic minorities and low SES populations (Goodwin, 2017).

Although there are currently no prevalence rates available for New Zealand, Australia reports the highest prevalence rate (10%) of childhood FA in the world (Osborne et al, 2011; Prescott et al, 2013). Given the fact that New Zealand and Australia have previously reported similarities in allergy presentation, such as egg being most common FA in children, which differs to most other countries where milk is the most common (Prescott et al, 2013), it seems a fair assumption that prevalence rates will likely be very high in New Zealand also. This being said, it is important to gain accurate data on FA in New Zealand so healthcare and support services can be tailored for these families.

### *Increasing Prevalence of Food Allergy*

Although gaining accurate prevalence rates from research is challenging, due to lack of objectively assessed reliable data, FA rates appear to be increasing (Sicherer & Sampson, 2018) particularly in Western countries such as the United Kingdom, Australia, and the United States (Quigley & Sanders, 2017; Tang & Mullins, 2017). The causes for this increasing prevalence remain

unclear, although a number of hypotheses are currently being investigated, such as Vitamin D deficiency, hygiene, and dual allergen exposure theories (Du Toit et al., 2018). In a study of approximately 5300 United States households, Sicherer and colleagues (2010) found tree nut and peanut allergies have been increasing consistently in children younger than 18 years between 2002 and 2010, but not in adults with these allergies, where rates remained relatively constant over time. Similarly, a large study of school students in over 1500 Australian schools identified increasing rates of children at risk for anaphylaxis between the years 2009 and 2014 (Loke et al., 2016). Using United States data from the National Health Survey, Jackson and colleagues (2013) reported that FA prevalence rates in children under the age of 18 years rose from 3.4% to 5.1% between the years of 1997 to 2011. A study of general practices in the United Kingdom revealed prevalence for people with peanut allergy doubling between the years of 2001 and 2005, although overall this prevalence is lower than that reported in previously mentioned studies at 0.51 per 1000 cases, perhaps due to underreporting by General Practitioners (Kotz, Simpson & Sheikh, 2011).

It is thought that FA prevalence rates will continue to steadily rise in developing countries as they start to adopt a more Westernised lifestyle (Tang & Mullins, 2017). The increasing prevalence is particularly noticeable in older children and adolescents, which is concerning given the rate of fatalities are highest in this age group (Bock, Muñoz-Furlong & Sampson, 2007). It is thought that this prevalence will continue to rise globally over the short to medium term until a cure for FA or effective treatment is discovered (Tang & Mullins, 2017).

### *Costs of Food Allergy*

Although data on the costs of FA for New Zealand families has not yet been documented, preventing and treating FA in children costs nearly 25 billion dollars a year in the United States alone (Bilaver et al., 2016; Gupta et al., 2013). The majority of these costs are carried by the families and include lost labour due to needing to take time of work to care for these children, and out-of-pocket expenses such as specialty foods (Gupta et al., 2013). Unfortunately, in New Zealand there is no



funding for the cost of adrenaline auto-injector (AAI) (commonly referred to as an EpiPen in New Zealand), which may mean the cost for many New Zealand families with allergy is even higher than countries such as Australia where families can receive two funded EpiPens on prescription if they meet specific criteria (Kemp, 2003).

In addition to the economic costs of FA, there is a very real form of emotional cost to managing this illness. Specifically, research has shown that the sense of burden related to looking after children with FA is also increasing. Specifically, in a global survey of existing data on FA, Prescott and colleagues (2013) found that none of the 89 countries investigated reported a declining FA-related burden. Due to rates of FA, New Zealand and Australia were both considered high-burden countries, but worryingly, had the lowest rates of specialist care with less than three pediatric allergists per million people. These rates suggest that majority of New Zealand families with FA will be unable to access face-to-face specialist care for allergy management, as these few doctors will likely be based in main city centres.

### *Treatment of Food Allergy*

In the absence of a cure for FA, which has yet to be identified, research has been focused on preventative treatment. Although there has been some success with this approach, such as oral immunotherapy (Bégin et al., 2014), these therapies are currently only available in research settings in Australia and New Zealand, and their safety and efficacy are still being established (Sampath, Sindher, Zhang & Nadeau, 2018). Thus, at present there is no publicly available cure for FA, and the mainstay of management involves constant vigilance and strict avoidance of the allergen, such as by constantly monitoring food labels in case commercial food products, which may have been safe, have had allergens added to them.

In order to maintain the aforementioned vigilance required to keep children with FA safe, constant label checking and trust in manufacturers is necessary for families with FA. Strict avoidance can be difficult, since common allergens such as milk and egg are found in many commercial food

products. This problem is compounded as there is a large variation in clear labelling of these products, which requires constant ingredient checking by children, adolescents, and caregivers. Consequently, the primary means for treating FA is a vigilant avoidance of allergens typically contained in foods (Bollinger et al., 2006).

Research shows that while there have been improvements in labelling issues, there is still evidence of serious problems. For example, an Australian and New Zealand study found that 10% of a sample of food allergic individuals had experienced allergic reactions due to unexpected traces of allergens in food, and 5% reported reactions due to incorrectly labelled commercial food products. Further, 20% of the sample stated that they often or always felt unsure about the food being safe for them when reading labels (“Consumer study on Food Allergen Labelling”, 2009). An earlier study found 30% of respondents reported that they have contacted the manufacturer to check ingredients in food items, indicating clarity of information is still a big issue for families with FA (“Quantitative consumer survey”, 2003). However, research indicates those with FA in New Zealand and Australia report more care in always reading labels for foods than do respondents from the United States (Vierk, Koehler, Fein & Street, 2007).

To gain a better understanding of the time families with FA spend on illness related issues, it is important to examine how FA is managed and treated. Once a child has been exposed to an allergen and has experienced an allergic reaction, this is usually treated with antihistamine for a mild reaction, or with adrenaline, such as via an EpiPen, for severe reactions, which will be followed up with hospital care in case of need for subsequent treatment (Sampson, 1999).

The most severe type of objective reaction to food is anaphylaxis, a severe, multi-systemic reaction which may result in death, with an estimate of 1.32% of people affected by this condition over their lifetime in England (Sheikh, Hippisley-Cox, Newton & Fenty, 2008) and 0.5-2.00% in the United States (Lieberman et al., 2006). Children and adolescents appear to be at greater risk for anaphylaxis (Lieberman et al, 2006). Biphasic allergic reactions, where allergic symptoms reoccur following initial symptom recovery, can occur up to 24 hours after the initial reaction (Lee & Greenes,

2000). These are more likely to occur in severe allergic reactions, therefore children who have experienced life-saving treatment may be monitored in hospital for several hours post recovery (Lieberman, 2005).

Parent's concern that their child might die from an allergic reaction is a very real phenomenon. Frequency of fatal and near fatal reactions has increased over time (Sampson, 1992). In a study by Sampson (1992) reporting on 13 children with fatal or near-fatal reactions to foods, accidental ingestions were common. Half of the six fatalities had been prescribed epinephrine but not one child had the device on them at the time of the reaction, with the majority of reactions occurring at school. These alarming statistics highlight the problem of relying on constant vigilance and avoiding allergens as the mainstay of FA treatment. It also indicates that schools may not be well-equipped to deal with very severe allergic reactions, and children may be unreliable at constantly carrying their Epipen. These problems are not unique to populations from the United States, as evidenced by an Australian survey that revealed how two thirds of school-aged children with a history of anaphylaxis did not have Epipens available at school in conjunction with an emergency action plan and a staff member able to administer adrenaline (Boros, Kay & Gold, 2000).

Accidental exposure to FAs, resulting in anaphylaxis, is the leading cause of adverse events in FA globally, with an estimated 30,000 episodes of anaphylaxis to foods (e.g., nuts, treenuts, fish, shellfish), resulting in emergency room treatment every year in the United States alone (Sampson, 2003b). An Australian survey revealed one in 166 school-aged children have previously experienced anaphylaxis (Boros et al., 2000), however fatalities from anaphylaxis are rare with estimates of one fatality per 3 million people every year (Moneret-Vautrin, Morisset, Flabbee, Beaudouin, & Kanny, 2005). In New Zealand, two FA-related fatalities have been documented between the years 1985 and 2005 (Low & Stables, 2006).

Despite the constant label checking in vigilance most families undertake every day, mistakes inevitably will happen. Foods may be incorrectly labelled, ingredients on trusted foods may change without families realising, children may be fed an allergen by somebody unaware of the seriousness of

their allergy, or children may find and consume a food not safe for them. For children with a history of severe reactions, or clinical testing which indicates they may be at risk for a severe reaction, carrying an AAI is absolutely essential to keep them safe (Muraro et al., 2014).

Although the requirement for carrying an AAI is obvious, if there is history of a very severe reaction needing life-saving intervention, determining the need for others with FA is more complex. FA research reveals large differences in criteria for needing to carry an AAI, which may act to confuse these families, create unnecessary stress if they are actually unlikely to need to carry one, and conversely, put children at risk by not prescribing an AAI in spite of them having risk factors for very serious reactions. In a study of adults with FA in the Netherlands, the authors revealed a tendency for AAI's to be overprescribed in patients presenting with mild allergic symptoms but underprescribed in those with serious reactions. Specifically, AAI's were only prescribed to 39% of patients following a severe allergic reaction presenting to their General Practitioner, and 60% of those presenting at an emergency department. It was also found that AAI's are being prescribed without proper advice and training and there is evidence of confusion over when to use AAI's and corticosteroids (Le, Hoffen, Pasmans, Bruijnzeel-Koomen & Knulst, 2008). Furthermore, patients have been shown to misjudge the necessity to seek emergency care for allergic reactions with many seeking emergency department care for both minor and severe reactions (Le et al., 2008). Similarly, in a study investigating the prevalence of tree nut and peanut allergies in the United States, researchers found only 46% of children and even fewer adults were prescribed AAI's despite nearly three quarters of the sample having previously experienced multi systemic allergic reactions (Sicherer, Muñoz-Furlong & Sampson, 2003).

In a related study by Pinczower and colleagues (2013), results indicated that carrying an AAI was associated with poorer HRQoL, and that this was independent of previous anaphylaxis and likely multifactorial in nature. Conversely, nearly three quarters of the parents in a study by Allen, Bidarkar, vanNunen & Campbell (2015) reported that carrying an AAI actually reduced stress and anxiety. The authors suggested that the high level of training this group of parents had received in relation to using

an AAI could account for why carrying an AAI actually helped, rather than hindered, their day to day lives. (Allen et al., 2015).

### *Parental burden and Food Allergy*

One factor that may exacerbate problems in families with FA that are already exhibiting high levels of anxiety is a sense of parental burden relating to managing FA. Recently, a focus of FA research has been investigating this disease burden in parents of children with FA. The Food Allergy Quality of Life- Parental burden Scale (FAQL-PB) scale is currently the only FA-specific measure of disease burden for parents (Cohen et al., 2004). Research has revealed parents of children with FA report a high sense of burden related to looking after their children. Nearly half of parents in a recent study investigating FA-related burden reported moderate to severe limitations in caring for their family, such as planning social activities, eating out, and entrusting their children's care to others. One of the factors shown to affect parental burden the most is parenting children with multiple allergies or those with severe reaction histories (Allen et al., 2015). In fact, its relationship with burden is stronger than needing to carry an AAI constantly, which is another factor known to increase stress on families with a child with FA (Pinczower et al., 2013).

Other studies have shown FA has a significant impact on the day-to-day lives of families, affecting family social activities, meal preparation, school attendance, and family stress levels. In fact, research by Bollinger and colleagues (2016) showed approximately 10% of these families choose to home school their children due to their concerns about keeping their children safe. Parents also admitted avoiding school camps, school outings, sending children to preschool or day-care, going to restaurants, letting their children go to friend's houses for play dates, camps, and sleepovers. Valentine and Knibb (2011) found that the burden of responsibility for caring for children with FA affected parents much more than children. This suggests parents may be taking on the bulk of day-to-day management to the extent of shielding their children from many of the FA-associated challenges. In a similar study, Springston and colleagues (2010) found a wide variation in scores on the FAQL-

PB, with nearly all participants at least moderately troubled by social interactions and limitations.

These authors also found that parental burden was higher for parents of children with multiple allergies and burden rates were very high. For example, approximately 65% of the sample felt moderately or extremely troubled by the extra time required to prepare safe meals.

Because there have been mixed findings into the precursors of maternal anxiety in parents of children with FA, it has been suggested that it is the daily burden of looking after children with FA rather than previous experiences, such as the severity of previous reactions and hospital admissions for allergic reactions, that are the key drivers of anxiety in this population (Cummings et al, 2010). Burden may be even higher for families dealing with idiopathic anaphylaxis where the trigger is unknown and avoidance is impossible (Mandell, Curtis, Gold & Hardie, 2005). It is thought by some that overly cautious avoidance tactics, such as steadfastly avoiding foods with a ‘may contain’ warning may increase a sense of burden (Shaker, Shwartz & Ferguson, 2017). In families instructed or opting to avoid all ‘may contain’ foods, the burden of painstakingly checking ingredients and dealing with inadequate labeling of foods has been found to be associated with impaired QoL (Cummings, 2010).

### *Anxiety and Food Allergy*

It is clear from the literature that FA in children is problematic in a number of ways, largely due to the constant vigilance required by both children and their families. Intuitively, it would seem likely this constant vigilance may result in increased anxiety for children given the tight control required around activities that usually bring joy, such as birthday parties and other social gatherings. Research has identified that FA does appear to impact a child’s level of anxiety, although this finding is inconsistent, suggesting a need for a larger pool of global research into the effect of anxiety in FA child populations. Lyons and Forde (2004) found that adolescents with FA exhibited higher anxiety levels than published norms of high school students in the United States. Similarly, Avery and colleagues (2003) found that children with peanut allergy had higher levels of anxiety than a control

group of children with insulin-dependent diabetes mellitus, especially fears relating to accidental ingestion and general anxiety about eating and managing their FA. However, other studies have shown that children with FA had comparable or even lower anxiety scores overall than those in healthy norm populations (Cummings et al., 2010; Le et al., 2013; King et al., 2009; Roy & Roberts, 2011).

Although LeBovidge, Strauch, Kalish, & Schneider (2009) found that children reported similar levels of anxiety to previously reported healthy norm populations, parents reported higher levels of anxiety in their children, especially when they had high symptoms of anxiety themselves. Given that parental overprotection has been linked to higher levels of child anxiety, and the necessity for parents to model non-anxious coping behaviours (Ginsburg & Schlossberg, 2002), providing parents with adequate psychoeducation relating to both management of FA, and ways to model healthy ways of coping, is important in protecting children with FA who may be at risk for high anxiety.

Similarly, anxiety can extend beyond the child and impact parents, especially mothers (King et al., 2009; Lau et al., 2014). It has been argued that both a lack of information about managing allergies and the uncertainty parents of children with FA face daily is a key driver of anxiety (Kemp, Allen & Campbell, 2009). This makes sense because parents seldom know when they are going to be faced with a child's allergic reaction, or how severe it is going to be. This may result in parents feeling 'on edge' on a daily basis. Many families experience periods of heightened anxiety, such as on immediate diagnosis of FA (Gustaffson et al., 2002), and periods of calm, when they experience a healthy adaptation to life with FA (Klinnert et al., 2014). A qualitative study by Mandell, Curtis, Gold and Hardie (2002) of 17 children who had experienced anaphylaxis and their parents, found fear and anxiety often increases during transitions, such as the time a child with FA starts school. It is thought that this may be due to an inability to relax when young children are away from their parents immediate supervision (Gillespie, Woodgate, Chalmers & Watson, 2007) and increased risk of exposure to allergens outside the home environment.

There is a growing literature supporting the argument that FA in children is related to increased anxiety in parents. For example, King and colleagues (2009) investigated anxiety in a sample of 46 parents of children with peanut allergy and found mothers reported significantly higher anxiety levels than both fathers in the sample and reported norm scores. The authors surmised that this might be due to mothers taking on the bulk of FA-related tasks such as purchasing foods (i.e., requiring careful label-checking) and preparing meals. Another study conducted by Cummings and colleagues (2010) of children with allergy to nuts found mothers had higher trait anxiety, representing a general tendency to feel anxious (Spielberger, 1973), than norm scores. Counterintuitively, they found severity of allergy was not significantly related to parent anxiety, nor was having a prescription for an AAI. In fact, the researchers found having an AAI prescription appeared to reduce anxiety, suggesting carrying one of these devices may help alleviate some fear parents feel about a future reaction, and their ability to cope with this challenge (Cummings et al., 2010).

Although the research has shown that parents of children with FA generally score higher than healthy norms for anxiety (Cummings et al., 2010), it has been argued that there may be an optimal level of anxiety for parents of children with FA in order to keep children safe and that a certain amount of overprotection is appropriate in children, especially those with a history of anaphylaxis (Warren, Otto, Walkner & Gupta, 2016). Therefore, finding an optimal balance between vigilance and risk is necessary. However, as the researchers pointed out, this is likely to differ between families and children given variability in FA presentation in children (Warren et al., 2016), as well as differences in family risk perception and perhaps their access to specialty care and support groups. Events out of the ordinary have been described as the most anxiety-provoking, such as sleepovers, parties and holiday celebrations, and transition periods, such as entering adolescence (Gillespie, Woodgate, Chalmers & Watson, 2007).

It has been argued that appropriate levels of anxiety could be helpful in effective allergy management by parents, such as engaging in support-seeking behaviours (Mandell, Curtis, Gold & Hardie, 2005). A lack of anxiety is thought to be a risk factor for failing to take the necessary steps in



keeping children with FA safe from accidental ingestion by avoiding problem foods and carrying an AAI (Knibb et al., 2012). However, one study has shown that higher levels of anxiety did not actually result in increased adherence to allergy plans (Cummings et al., 2010). Conversely, Mandell and colleagues (2005) found low anxiety levels was related to decreased vigilance and being prepared for a future allergic reaction. Clearly, more research is needed to provide clarity about the protective nature of appropriate levels of anxiety in parents of children with FA to shield them from undue risk.

### *Health-Related Quality of Life*

As well as the physical ramifications already detailed above, FA can also impact the lives of children in social, academic, psychological and socio-emotional ways (Chow et al., 2015; Cummings et al., 2010; Knibb & Stalker, 2012). These dimensions are captured by the construct of Health-Related Quality of Life (HRQoL). HRQoL can be described as an individual's perception of the influence of health status on physical, psychological, and social functioning, which is multidimensional and subjective in nature (Matza, Swensen, Flood, Secnik, & Leidy, 2004). HRQoL also has positive (e.g., contentment) and negative (e.g., pain) dimensions (WHOQoL group, 1995) and can be influenced by both internal (e.g., mental health) and external factors (e.g., physical environment; Warren et al, 2016). Valid and reliable HRQoL measures have clinical relevance that can help both patients and practitioners make informed treatment choices (Higginson & Carr, 2001).

Because children have unique contexts (e.g., family, school, peers) that can mediate the impact of chronic disease, child measures of HRQoL need to capture this fact. This is paramount in allergy research with children as this condition has a significant effect on the way they are able to interact with their peers due to social limitations (e.g., attending play dates, attending birthday parties, etc.). Fortunately, psychometrically rigorous generic HRQoL measures exist that are designed to examine a broad range of outcomes and measure the impact chronic disease has on overall functioning. It is no surprise that both adults and children with FA report significantly lower levels of HRQoL than their

healthy counterparts (Primeau et al., 2000; Valentine & Knibb, 2011) and children without FA (King, Knibb & Hourihane, 2009).

A range of generic HRQoL measures have been used in FA populations, such as the Pediatric Quality of Life Inventory (Varni, Seid & Rode, 1999) for children, and the World Health Organisation Quality of Life assessment (The WHOQOL group, 1998) for adults (Chow et al., 2015 Valentine & Knibb, 2011). Unfortunately, there is a lack of FA-specific measures for children and adolescents resulting in researchers using parent proxy reports of child HRQoL for those with FA, such as the Food Allergy Quality of Life Questionnaire-Parent Form (DunnGalvin, de BlokFlokstra, Burks, Dubois & Hourihane, 2008).

Intuitively, it would seem that children with FA and experience with life-threatening allergic reactions likely have impaired HRQoL. Research supports this hypothesis. For example, Avery and colleagues (2003) found that children with peanut allergy reported significantly lower HRQoL than a control group of children with insulin dependent diabetes mellitus. With that being said, it is still unclear whether specific FAs, such as peanut, have a greater impact on children's HRQoL. DunnGalvin and colleagues (2008) did find that children with a peanut allergy had HRQoL that was impacted more than those with a different single allergy or even multiple allergies, with the author's suggestion that this finding is due to the challenge in avoiding this allergen and required vigilance.

Another study investigating HRQoL in children with peanut allergy by King and colleagues (2009), found these children had significantly poorer HRQoL than did their siblings without FA, as well as published healthy norms, with domains of school and physical health particularly impaired. Similarly, a study of 253 children by Sicherer and colleagues (2001) with FA found HRQoL to be significantly worse than previously established healthy norms. Conversely, a study by Valentine & Knibb (2011) that utilised a group of children with FA as well as control group of children without FA, found only some children with FA had poorer HRQoL than the control group, with the majority reporting similar or better HRQoL to children without FA. However, caregivers in this study reported

significantly poorer HRQoL than both the control group of parents whose children did not have FA, and the children themselves.

In families with FA, some parents experience levels of stress and distress that may affect the overall family functioning and ability to adapt to life with FA. Although some parents are able to achieve a sense of emotional distance and normality from the challenges associated with FA, research has shown repeatedly that parents of children with FA are challenged by negative emotions such as guilt and excessive worry (Valentine & Knibb, 2011; Vickers, Maynard and Ewan, 1997).

Unfortunately, these emotions can have an impact on their child, which was illustrated in a study of 533 mothers of children with FA. Specifically, Chow and colleagues (2015) found that the severity of the child's allergy, maternal overprotection, and psychological distress were all significantly associated with poorer quality of life and/or functioning in their allergic children. Furthermore, children of mothers who were more stressed had a stronger relationship between AAI use and child anxiety than did children of less-stressed mothers. This research has helped provide a better understanding of how improved screening measures are needed to identify those at risk for further difficulties, both in terms of the child's difficulties and maternal distress, which may be impacting the child's QoL (Chow et al., 2015).

### *Theoretical Frameworks and Food Allergy*

In order to better understand the association between FA and associated psychological variables such as HRQoL and anxiety, it is necessary to investigate underlying theories that may help explain certain responses to allergic life and the maintenance of specific behaviours related to FA coping. While no theoretical models specific to FA have been universally adopted, which makes it difficult for researchers to effectively develop prevention and treatment measures for the psychological effects of FA (DunnGalvin, Gaffney & Hourihane, 2009), Cognitive-Behavioural Theory (CBT) has been utilised to understand how maladaptive thought patterns can contribute to the development of anxiety in FA populations. Specifically, as children learn more about their FA, and

the specific reaction they can expect when exposed to certain allergens, it is easy to imagine how a maladaptive pattern of thinking can develop. For example, children may begin to perceive potential “threats” in multiple settings, imagine fatal outcomes with any exposure, etc. As this pattern of thinking becomes more solidified, cognitively, this may subsequently impact the child’s behaviour and certainly their emotions (e.g., anxiety). In fact, cognitive behavioural treatment has been recommended with a focus on isolating individual coping strengths and using emotional, behavioural and cognitive adaptive approaches to manage FA in order to relieve feelings of distress related to their condition (Polloni et al., 2015a).

Further, the potential impact that parent behaviours can have on the development of this type of maladaptive thinking pattern is easy to see. Thus, utilizing elements of Social Learning Theory (SLT) can also be seen as another means for understanding these psychological phenomena. In fact, asthma research has suggested an association between high maternal anxiety and child anxiety (Gupta, Mitchell, Gluffre & Crawford, 2001), and the aforementioned SLT framework may be one means for understanding this finding better. Specifically, it has been suggested that maladaptive coping skills and overprotection exhibited by parents in response to stressful allergic experiences can result in children modeling anxious behavioural responses seen by their parents (Friedman & Morris, 2006).

In addition to the aforementioned CBT and SLT frameworks, other researchers have postulated other conceptualizations to help explain the relationships between FA and anxiety. Following a qualitative enquiry, DunnGalvin (2009) has proposed an integrated developmental framework in an attempt to understand maladaptive coping strategies utilised by children with FA in order to devise clinical interventions which can be targeted to this population. This framework was organised into six main themes, and is explained from a developmental point of view. These themes were peer relationships, risk and safety, coping strategies, meaning of food, control and self-efficacy and self/identity. Although this research and proposed framework is promising in planning for effective healthcare, as yet, this framework has not been globally adopted or used in research to help understand psychological findings related to children with FA.

The aforementioned research has clearly shown how FA can have a significant impact on a range of psychosocial variables such as HRQoL and anxiety. However, a very limited body of research has focused on psychological interventions designed to improve functioning in either children or parents of children with FA. In a study measuring the efficacy of FA-related interventions, Baptist and colleagues (2012) utilised a blind randomised controlled trial design to investigate a self-regulation intervention for parents of children with FA. This intervention involved three 25-minute telephone calls by a nurse trained in self-regulation pertaining to FA. The calls discussed FA related concerns, goals and barriers, and then devised strategies to overcome the barriers. Devising and developing coping mechanisms and strategies for living with FA were a key part of this intervention. At enrolment, 58 parent-child dyads were randomly assigned to either an intervention or control group and each family completed a measure of FA-specific parent perceived burden (i.e., FAQL-PB questionnaire; Cohen, Noone, Muñoz-Furlong & Sicherer, 2004). Results indicated statistically significant improvements on the FAQL-PB scale post-intervention. Specifically, domains of frustration, helplessness, anxiety and confidence were each significantly better post-treatment.

Clinical interventions using a CBT framework have recently been trialed to examine changes in adaptive coping skills as a means for reducing anxiety in FA populations. Specifically, a randomised clinical trial of 200 participants in the United Kingdom by Boyle and colleagues (2017) found that a single session of CBT improved anxiety and stress in mothers of children with FA a year following treatment. The trial included psychoeducation with elements of risk information, relaxation training, and cognitive restructuring. The authors suggested this work around risk perception may have been responsible, or partly responsible, for reduced maternal anxiety at the one year follow up given the likelihood of mothers' constant worrying about negative outcomes. The authors stated that health workers have a tendency to exaggerate the risk of fatal anaphylaxis when passing on risk information to families, which acts to increase anxiety. Therefore, it was suggested there be a stronger emphasis on accurate risk information being passed on at critical times such as when parents

receive a prescription for an AAI (Boyle et al., 2017), but for families who have persistently problematic levels of anxiety, a short psychological intervention utilising CBT may be helpful in reducing anxiety.

The nature of FA in families means that caregivers are trying to keep their children safe through constant vigilance (Klennert & Robinson, 2008). However, as highlighted above, many parents are also trying to manage their own stress, anxiety and decreased QoL associated with parenting a child with FA (Cummings et al., 2010). Surprisingly, very few studies have investigated interventions designed to address the family system among families with a child diagnosed with FA. Thus, exploring the role of the parent, and the impact parent factors can have on child outcomes (e.g., HRQoL) can be seen as a critical next step in this line of research.

### *Limitations*

There are a number of limitations to the reported studies. Firstly, very few studies used both parent and child reports of child HRQoL despite the most commonly used measure, the PedsQL™, offering both child report and parent proxy forms for child HRQoL. One study used parent report only of child HRQoL (Chow et al., 2015); while most used just child reported HRQoL (Shemesh et al., 2013; Valentine & Knibb, 2011). This can be seen as problematic as parents who feel a great sense of burden in looking after their child with FA may overestimate the impact of FA on their child's HRQoL. Conversely, it is possible that parents do not actually realise the true impact of FA and will under report the impact on their child's HRQoL. Given caregivers inability to physically feel their child's pain for ongoing allergic symptoms as well as the frustration of continually watching their child missing out in social situations involving food, it is possible children will actually rate their HRQoL as poorer than would their caregivers. Parents may also put isolated allergic experiences into perspective better than children for developmental reasons. Using both child self-report and parent proxy report, such as the present study aims to do, could result in a more accurate portrayal of the effect of FA on HRQoL in children.

Another limitation, that is likely due to the fact that this body of research is in its infancy on some level, is that only a handful of studies have measured HRQoL among children with FA (Marklund et al., 2004; Valentine & Knibb, 2011; Warren et al., 2015). Similarly, very little research exists that examines child anxiety (Cummings et al., 2010; Goodwin et al., 2017), parent anxiety (Cortes et al., 2018; Cummings et al., 2010), parental burden (Cohen et al., 2004; Leung, Yung, Wong, Li & Wong, 2009; Primeau et al., 2000; Warren et al., 2015) and moderating effects on child HRQoL (Chow et al., 2015) in children with FA and their parents.

Further, there is a very limited body of quantitative research examining FA in children from New Zealand. Research examining adults with FA has resulted in findings similar to those found internationally with children. Specifically, research has shown that individuals with FA have significant difficulty eating safely, experience significant costs related to FA (i.e., emotional, financial), experience the burden of constant vigilance, experience fear and anxiety, perceive a lack of public awareness related to the seriousness of FA (e.g., restaurant staff), and experience feelings of isolation (Peniamina, Bremer, Conner & Miroso, 2014).

### *Rationale for the Present Study*

Previous literature has demonstrated that the HRQoL is impaired in children with FA and that children with more severe allergies evidence poorer HRQoL. The research also indicates that parents of children with FA feel a great sense of burden and often experience high levels of anxiety. However, no study to date has attempted to measure the relationships between these variables, and certainly not in a sample of children from New Zealand. The present study will expand the literature by investigating the relationships between FA severity, anxiety, parent perception of burden, and child HRQoL in a New Zealand population. Ultimately, this investigation aims to identify important variables that moderate the potential impact FA severity has on anxiety, parent perceived burden, and child HRQoL. This research may inform evidence-based interventions that are designed to improve the HRQoL for children with FA.

*Research Hypotheses*

1. Children with FA will demonstrate lower levels of HRQoL compared to reported norms of children without FA.
2. Children with more FA will demonstrate lower levels of HRQoL compared to children with one or two FAs.
3. Severity of FA will be associated with lower levels of child HRQoL.
4. Primary caregiver's anxiety will moderate the relationship between FA and HRQoL, such that higher levels of anxiety, relative to lower levels, will be associated with lower HRQoL (see Figure 1).
5. Primary caregiver's sense of perceived burden will moderate the relationship between FA and HRQoL, such that higher levels of Parental burden, relative to lower levels, will be associated with lower HRQoL (see Figure 2).



## Method

### *Participants*

Participants consisted of 154 dyads consisting of a parent/caregiver and their FA diagnosed child. Specifically, primary caregivers were defined as the individual who was responsible for the day-to-day responsibility of allergy-related care, (e.g., preparing meals, shopping for food, checking food labels, etc.) for children with FA aged zero to 18 years. Families were recruited from social media, quarterly magazines, email-based newsletters, and website advertising between August 2018 and December 2018. Recruitment was conducted via a collaboration between The University of Canterbury, Allergy New Zealand, and Coeliac New Zealand. Allergy New Zealand is a New Zealand based charity that offers information, education, and support to families with children who have Food Allergy ([www.allergy.org.nz](http://www.allergy.org.nz)). Their ultimate goal as an organization is to help children with FA live an active and healthy lifestyle. Coeliac New Zealand is a not-for-profit organisation that supports people with coeliac disease and those following a gluten free diet.

Inclusion criteria for the study required that participants be the primary caregiver of a child aged zero to 18 years who suffered from IgE-mediated food allergy, non-IgE-mediated food allergy, or food related immune disorders (e.g., Coeliac Disease) along with that child. Further, it was required that the child's FA be medically diagnosed, rather than self-diagnosed or diagnosed by the parent. In addition, children with issues that may have impacted their ability to complete the questionnaires and/or otherwise participate in the study (e.g., autism, developmental delays, etc.) were excluded and participants were required to understand and be able to write in English due to the fact that the previously validated measures being used were printed in English.

Advertisements included a brief description of the study, the primary researcher's contact information, and instructions related to requesting participation in the study (Appendix 1). Specifically, advertising and questionnaire instructions described how a FA diagnosis was required to

have been made by a medical professional, and this was screened again within the family information form where participants were asked who made their child's FA diagnosis, and what testing was used to verify this (e.g., skin prick testing RAST tests). Following receipt of the advertisement, interested families contacted the primary researcher by e-mail, at which point the researcher mailed a research packet that included necessary instructions (Appendix 2), consent (Appendix 3), assent (Appendix 4), and research questionnaires to the family. Advertisements by Allergy NZ and Coeliac New Zealand both targeted families with allergy throughout New Zealand and research packets were sent out Nationwide.

### *Procedures*

The current study was approved by the University of Canterbury Human Ethics Committee (Reference: HEC 2018/63; Appendix 5). Each family who expressed interest in participating via email correspondence received an envelope containing the research packet in the mail, which included research questionnaires and an information form describing the study and explaining the process of questionnaire completion. The research packet also included a Parent Consent Form, Child Assent Form, and a pre-paid self-addressed return postage envelope for returning the questionnaires to the research team. The packet also contained an allergy-themed wristband as a token of appreciation for the time each family dedicated to the study. Once the packet was received by the family, the primary caregiver was instructed to carefully read the information sheet prior to completing the forms. If the primary caregiver agreed to participate, they were asked to complete the Parent Consent Form. The instruction form also asked the primary caregiver to read the Child Assent Form to the participating child, if necessary, or asked the child to read it for themselves if they were capable of doing so. If the child also agreed to participate, they wrote their name at the bottom of the Child Assent Form. For children too young to write, their parents signed on their behalf if the children agreed to consent. Families that had more than one child with FA were instructed to complete the forms for the child they considered to have experienced the most severe symptoms.

For children ages zero to 18 years, the primary caregiver was instructed to complete a modified version of the PedsQ™ Family Information Form (Appendix 6), the Food Allergy Quality of Life-Parental Burden Scale (Appendix 7), and the State-Trait Anxiety Inventory (Appendix 8). For children ages five to 18 years, the target child was asked to complete the PedsQL™ Generic Core Scales (Appendix 9), and children ages eight to 18 years were instructed to complete the State-Trait Anxiety Inventory-Child form (Appendix 10). These tasks were estimated to take approximately 20 minutes in total. Once the forms had been completed, the caregiver was instructed to return all research materials in the supplied pre-paid envelope addressed to the research team, which completed their participation in this research.

### *Study Design*

The following investigation utilized a cross-sectional design to evaluate the relationships between several primary and secondary variables of interest. Specifically, primary variables of interest included child illness severity, child HRQoL, child anxiety, parent anxiety, and parent perceived FA-related burden. Ultimately, the moderating impact parent anxiety had on the relationships between child illness severity and HRQoL and the relationship between child illness severity and perceived burden were of primary interest.

### *Data Collection and Entry*

Once the research packets were received by the research team, they were opened and checked for completeness and filed by grouped identification numbers in a locked filing cabinet in the primary supervisor's office within the University of Canterbury Health Sciences building. In an effort to maximize recruitment efforts, a reminder email was sent two months later to all email recipients who had expressed interest in receiving a research packet but had not yet returned it. After this email a total of three families refused participation in the study for personal reasons relating to shared care. Consequently, of the 280 families who expressed interest in the study, 154 returned the questionnaires within four months, which represents a 55% response rate for those who expressed interest. It is

important to note, however, that data collection is ongoing and this response rate is increasing at present. Also important to note is that, due to the child anxiety measure being recommended for children eight years of age and older, no anxiety forms were completed for a portion of children in the sample. Anxiety forms were completed for 70 children in the study.

All data were entered into a software program for later analysis. Specifically, IBM SPSS Statistics version 25 (SPSS Inc., Chicago, IL) was used for data entry, coding, and analyses. First, a comprehensive data set was created that included each item from the research questionnaires. Responses for each questionnaire were entered into the database according to the individual questionnaire's manufacturer instructions if available. Specific categorical variables were created during the data entry process for individual allergies, comorbid conditions (e.g. eczema) and allergy symptoms (e.g. hives). Additionally, string variables were created for several answers from the family information form, such as the name of the child's medical condition, non-food-related allergies, who diagnosed the allergy and symptoms not related to allergy. These were not coded for the current investigation, but were used for preliminary descriptive statistical analyses. A variable for FA severity was calculated by summing frequency of anaphylaxis, the number of foods avoided, the number of symptoms experienced, history of ER visits and history of hospital admissions. This is a slightly modified method used by Chow and colleagues (2015) in a similar study that also examined a moderational model among in families with FA.

### *Measures*

#### Family Information Form

Demographic, allergy and additional family information was collected by parents using an adapted version of the PedsQL™ Family Information Form (Varni, Seid & Kurtin, 2001). Information collected included: (a) child age, gender, ethnicity, (b) parent occupation, marital status and education level, (c) number of days parents miss from work due to child's health, and number of

days children miss school due to their health, (d) details of the child's allergy diagnosis, other medical conditions, number and reason for emergency department (ER) visits and hospital admissions, siblings with FA, history of anaphylaxis, allergy symptoms, comorbid conditions (allergy, eczema, dermatitis), non-food allergies, specific food allergies, and whether the child requires an EpiPen. Again, please see Appendix 6 for the PedsQL™ Family Information Form.

Symptoms and signs entered in the database were a combination of subjective (e.g., nausea) and objective (e.g., urticaria, vomiting) symptoms reported by the primary caregiver and described in the family information form. The food that was known to elicit the child's FA, was recorded as 'unknown' in the database if the patient reported an inability to discover the culprit allergen. For example, if multiple foods had been eaten prior to the reaction and they were unsure what food had caused the reaction. Symptoms were assumed to be absent if they were not reported, and all information contained in the family information form was entered into the database.

#### Food Allergy Quality of Life-Parental Burden Form

Perception of parent burden was assessed with the Food Allergy Quality of Life-Parental Burden questionnaire (FAQL-PB; Cohen et al., 2004). This measure includes several areas of perceived burden that are relevant to caregivers of children who have FA, such as the time for preparing special meals (Bollinger et al, 2006). The FAQL-PB has 17 items and uses a seven-point Likert scale ranging from a one for low trouble to a seven for a lot of trouble regarding the burden for each item. Items include issues related to family life with FA, such as going away for holidays, dining out at restaurants, being able to work and put children in child care, time needed for meal preparation, health concerns, and emotional issues. The FAQL-PB also measures worry about and ability to help children experiencing an allergic reaction, fear about allergic reactions in the future, sadness about FA-related burden the child carries, and frustration (Cohen, Noone, Muñoz-Furlong & Sicherer, 2004). Scoring for the FAQL-PB involves entering the raw score for each item into the database and summing these to give a total continuous score. Higher scores indicate greater burden

experienced by the primary caregiver. Scores range from a 17 to 117, with mean total scores often calculated by dividing the total score by 17 (Knibb & Stalker, 2013). Previous research indicates that the FAQL-PB possesses strong psychometric properties. Specifically, studies have shown the FAQL-PB has excellent test-retest reliability (0.93; Cohen et al, 2004) and internal consistency ( $\alpha = 0.98$ ; Leung, Yung, Wong, Li & Wong, 2009).

#### PedsQL™ Generic Core Scales

To evaluate child HRQoL, parents and their children completed the Pediatric Quality of Life Inventory Generic Core Scales (PedsQL™). The PedsQL™ 4.0 Generic Core Scales are designed to assess generic HRQoL in children between the ages of two and 18 years, and include both parent-proxy and child self-report forms (Varni, Seid & Rode, 1999). Specifically, the PedsQL™ 4.0 Generic Core Scales include a parent proxy-report form for children ages two to four years of age, and both parent proxy-report and child self-report forms for children ages five to 18 years. Both the PedsQL™ parent-proxy and child self-report forms contain 23 items which include a Physical Functioning subscale (eight items) an Emotional Functioning subscale (five items), a Social Functioning subscale (five items), and a School Functioning subscale (five items). In addition to these four scales and a total scale score, the scores also can be used to calculate a Psychosocial Health Summary score which is a combination of the Emotional, Social and School Functioning scales. Both parent proxy-report and child-report scores were reverse scored and linearly transformed to a scale ranging from zero to 100 as recommended by the manufacturer (Varni, Seid & Kurtin, 2001). Higher scores on this transformed scale represent better HRQoL. The PedsQL™ 4.0 Generic Core Scales demonstrates excellent reliability ( $\alpha = 0.88$ ; Varni, Seid & Kurtin, 2001; Varni, Seid & Rode, 1999) and has been validated in both clinical and non-clinical samples (Varni, Burwinkle, Seid & Skarr, 2003; Varni, Seid & Kurtin, 2001).

### State-Trait Anxiety Inventory (STAI)

To evaluate anxiety in parents of this sample, caregivers completed the State-Trait Anxiety Inventory (STAI) for adults (Spielberger, Gorsuch & Lushene, 1970). The STAI is a self-evaluation questionnaire with two sections of 20 items, measuring both trait and state anxiety. Trait anxiety refers to an overall tendency to become anxious while state anxiety refers to the transitional feelings an individual is currently experiencing. The STAI measure can be used to give an overall low, medium or high anxiety rating (Boyle et al., 2017; Spielberger, Gorsuch & Lushene, 1970), although a score of 40 is often used as a cut-off point for separating participants into low and high anxiety groups (Addolorato et al, 1999). Versions exist in a variety of languages, including an English/New Zealand version where all items are rated on a four-point scale ranging from 'not at all' to 'very much so' for the state form and 'almost never' to 'almost always' on the trait form. Higher levels of anxiety are represented with higher scores, with a minimum score of 20 and a maximum 80 for both State and Trait anxiety sections (King, Knibb & Hourihane, 2009). Previous research indicates that the STAI possesses strong psychometric properties. Specifically studies have shown the STAI has excellent internal consistency ( $\alpha = .91$ ) and has been validated on both clinical and non-clinical samples (Crawford, Cayley, Lovibond, Wilson & Hartley, 2011; Spielberger & Edwards, 1973).

### State-Trait Anxiety Inventory for Children (STAI-C)

The State-Trait Anxiety Inventory for children (STAIC) (Spielberger & Edwards, 1973) is a 40-item self-evaluation questionnaire for children. Similar to the STAI, it distinguishes between fleeting anxiety, named state anxiety, and a tendency for anxiety embedded in personality, named trait anxiety. It is designed for children of eight years old and above to complete independently (Spielberger & Edwards, 1973). The STAI-C differs slightly to the STAI in that all items are rated on a 3-point scale ranging from 'hardly ever' to 'often' with a high score representing higher anxiety levels. For questions indicating presence of anxiety (e.g. upset, worried), the STAI-C State-Anxiety items are valued three, two or one whereas items indicating an absence of anxiety (e.g. calm, relaxed)

are scored a one, two or three. For the STAI-C trait anxiety form, each item indicates the frequency of behaviour occurrence, and thus all items are scored a three, two or one for *very often*, *sometimes*, and *hardly ever*. The scores for each scale range from 20 to 60. The STAI-C has also been validated on both clinical and non-clinical samples and has demonstrated excellent reliability ( $\alpha = .88$ ; Kirisci, Clark & Moss, 1997).



## Results

### *Preliminary Transformations & Analyses*

All preliminary transformations, preliminary analyses, and primary analyses were conducted using IBM SPSS Statistics version 25 (SPSS Inc., Chicago, IL). Following data entry as detailed above, the manufacturer and/or measure developers' instructions were followed relating to transformations, scoring and interpreting of summary scores.

First, demographic variables (e.g., participant age, gender, and ethnicity) were examined for descriptive purposes. Next, FA characteristics, such as associated symptoms, comorbid conditions (e.g., asthma, eczema), number of foods avoided were also examined for descriptive purposes and the means of major variables of interest (i.e., burden, anxiety, HRQoL) were calculated.

Next, Pearson correlations and ANOVA were conducted to determine the degree to which child age, gender, family income and ethnicity were related to measures of anxiety (i.e., parent as measured on the STAI and child anxiety as measured on the STAI-C), measures of parental burden on the FAQL-PB, both parent and child-reports of HRQoL (i.e., PedsQL™ Generic Core Scales for toddlers and children), and other parent reported variables. In instances where demographic variables were significantly related to primary variables of interest, those variables were controlled for in subsequent analyses where statistically appropriate.

For the current investigation, child age was significantly related with parental burden ( $r = -.24$ ,  $p = .01$ ), and child reported HRQoL ( $r = .21$ ,  $p = .05$ ). Child gender was significantly correlated with child anxiety ( $r = -.32$ ,  $p = .01$ ). Family income was significantly related with parental burden ( $r = -.16$ ,  $p = .05$ ), parent anxiety ( $r = -.23$ ,  $p = .01$ ), child anxiety ( $r = -.29$ ,  $p = .04$ ), and parent reported child HRQoL ( $r = .22$ ,  $p = .05$ ). Consequently, those demographic variables were controlled for in all analyses conducted using the aforementioned primary variables of interest.

### *Descriptive Statistics*

Demographic variables (e.g., child age, gender, ethnicity, family income) were examined for descriptive purposes and can be found in Table 1. The average child who participated in the study was 7.11 years of age and 51.3% were male. Parents in this sample described their child's ethnicity predominantly as New Zealand European (72.1%), Māori (15.8%), Asian (8.6%), Pacific Island (2.5%), European (1.9%) and British (1.9%). The median annual household income for the families participating in the study was between \$100,000 and \$150,000.

In terms of other descriptive statistics, the average number of foods avoided due to allergy for children participating in the study was 5.08 ( $SD = 3.80$ ), with number of foods avoided ranging from 1.0 to 30.0. The mean age at FA diagnosis was 1.49 years ( $SD = 1.97$ ) and 3.1% of the sample had been hospitalized over the previous 12 months due to their FA, while 19.9% had visited the Emergency Department for FA-related issues. Nearly one quarter of the respondents suffered from Coeliac Disease (24%), and almost all of the responding parents stated that their child's FA had been clinically diagnosed by skin prick/blood test, or biopsy for those diagnosed with Coeliac Disease (98.7%). For those with FA alone, the most common allergen was milk, and the most common FA-related symptom was hives. Details of common allergens and symptoms can be found in Table 2. Of the sample, 44.2 % had experienced at least one anaphylactic reaction due to their FA, with the number of episodes ranging from one to 30 ( $M = 1.49$ ,  $SD = 3.21$ ). A total of 24.7% of the children in the study with FA also had siblings with confirmed FA, and comorbid disorders were common among the sample (e.g., 67.5% suffering from eczema, 51.9% from asthma). Lower rates of other allergy-related conditions were found with just 1.9% reporting Eosinophilic Esophagitis (EOE) and 1.3% reporting Food Protein-Induced Enterocolitis Syndrome (FPIES). Finally, 55.2% of families reported carrying an auto-injector.

### Health-Related Quality of Life among Children with Food Allergy

To determine if significant differences existed between children with FA, when compared to their non-FA counterparts, the present sample means for total scale score and subscale scores on the PedsQL™ were compared with published means for healthy controls (Varni, Burwinkle, Seid, & Skarr, 2003). Specifically, two T-Tests were conducted that examined differences of parent proxy-reported and self-reported child HRQoL among children with FA and healthy controls. As hypothesized, results indicated that child self-reported HRQoL total scale scores and subscale scores were significantly lower than healthy controls among the current sample (see Table 5). In terms of parent reported child HRQoL, results indicated that total scale scores and emotional, social and psychosocial subscale scores were significantly lower than the healthy controls. However, contrary to anticipated results, children with FAs physical and school subscales scores were not statistically significant different to healthy controls (see Table 5).

### Multiple Food Allergy and Health-Related Quality of Life

To test the hypotheses related to the impact FA has on HRQoL, a series of regression analyses were conducted. Specifically, to determine whether the total number of food allergies impacted child HRQoL, two linear regression analyses were conducted. First, a regression analysis was conducted with the parent reported total number of foods avoided as the independent variable and the child reported PedsQL™ total scale score as the dependent variable. Results indicated that the number of foods avoided by children with FA was not a significant predictor of self-reported child HRQoL,  $F(2,92) = 2.17, p > .05$ . For the second regression analysis, parent reported total number of foods avoided was entered as the independent variable and the parent reported PedsQL™ total scale score as the dependent variable. Again, results indicated that the number of foods avoided by children with FA was not a significant predictor of parent-reported child HRQoL,  $F(1,94) = .46, p > .05$ .

### Food Allergy Severity Impact on Child Health-Related Quality of Life

To determine whether the severity of a child's FA impacted his or her HRQoL in the present sample, two linear regression analyses were conducted. The first regression analysis included entering the FA severity variable as the independent variable and child reported PedsQL™ total scale score as the dependent variable. Results indicated that FA severity was not a significant predictor of self-reported child HRQoL,  $F(2,92) = 2.87, p > .05$ . For the second regression analysis, the FA severity variable was entered as the independent variable and the parent-proxy PedsQL™ total scale score as the dependent variable. Results from this analysis indicated that FA severity significantly predicted parent reported child HRQoL,  $F(2, 93) = 3.45, p < .05$ , such that the more severe the FA the worse the parent reported child HRQoL.

#### *Moderation Analyses*

To test the hypothesis related to illness severity, child HRQoL, parental anxiety and parental burden, moderation analyses were conducted. Specifically, hierarchical linear regression analyses were performed to examine whether parent anxiety and/or parental burden would moderate the relationship between FA severity and both parent and child reported HRQoL. For the first analysis, FA severity, parent anxiety and parental burden scores were transformed to Z scores. Next, two interaction terms were created by calculating a variable that was the product of the FA severity and parent anxiety Z scores, and the product of the FA severity and parental burden scores. Finally, testing each model consisted of analyses that were conducted at three levels: 1) variables being controlled for (e.g., child age, family income) were entered into Step 1, 2) main effects (e.g., FA severity and parent anxiety or parental burden) were entered into Step 2, and main effects (i.e., interaction terms) were entered into Step 3. Any significant interactions would be examined post-hoc with probing to determine the nature of the interaction.

### Child-reported Health-Related Quality of Life

Results from the first moderation analysis indicated that, contrary to the proposed hypotheses, no significant FA severity by parent anxiety interactions in the prediction of self-reported child HRQoL. That is, parent anxiety did not moderate the relationship between severity of FA and child HRQoL ( $B = 2.03$ ,  $SE = 1.53$ ,  $\beta = .14$ ,  $p > .05$ ). Similarly, results from the second moderational analysis indicated no significant FA severity by parental burden interactions in the prediction of self-reported child HRQoL. Specifically, parent anxiety did not moderate the relationship between severity of FA and child reported HRQoL ( $B = 1.28$ ,  $SE = 1.70$ ,  $\beta = .07$ ,  $p > .05$ ).

### Parent-reported child Health-Related Quality of Life

Results from the moderational analysis related to parent reported child HRQoL indicated no significant FA severity by parent anxiety interactions in the prediction of proxy-reported child HRQoL. That is, contrary to the hypotheses for the current study, parent anxiety did not moderate the relationship between severity of FA and child HRQoL ( $B = 2.19$ ,  $SE = 1.75$ ,  $\beta = .13$ ,  $p > .05$ ). Similarly, the final moderation analysis indicated no significant FA severity by parental burden interactions in the prediction of proxy-reported child HRQoL; parent anxiety did not moderate the relationship between severity of FA and child HRQoL ( $B = 0.62$ ,  $SE = 1.86$ ,  $\beta = .29$ ,  $p > .05$ ). Due to the lack of statistically significant moderation findings, no post hoc probing needed to be performed. Tables 6-9 provide the step-by-step statistics for these regression analyses.

## *Secondary Analyses*

### Food Allergy Severity Impact on Anxiety

In light of the finding that parent anxiety did not moderate the relationship between illness severity and child HRQoL, secondary analyses were performed to examine the direct relationship between FA severity and anxiety more carefully. Specifically, to determine whether the severity of

the child's FA impacted anxiety in the present sample, two linear regression analyses were conducted. The first regression analysis included entering the FA severity variable as the independent variable and child STAI-C trait anxiety subscale total score as the dependent variable. Results indicated that FA severity was indeed a significant predictor of child anxiety,  $F(3,65) = 3.77, p = .01$ , such that the more severe the FA the greater the child anxiety was. For the second regression analysis, again the total FA severity variable was entered as the independent variable, but parent trait anxiety subscale score was entered as the dependent variable. Contrary to the first regression, results from this analysis indicated that the severity of the child's FA did not predicted parent anxiety,  $F(2,138) = 3.97, p > .05$ .

#### Food Allergy Severity Impact on Parental Burden

Given the lack of significance for the moderation analysis related to illness severity, parental burden, and child HRQoL, secondary analyses were conducted. Specifically, to determine whether illness severity impacted parent-perceived burden in the present sample, a single linear regression analysis was conducted where illness severity was entered as the independent variable and parental burden was entered as the dependent variable. Results indicated that FA severity was a significant predictor of parental burden,  $F(4,130) = 7.28, p < .01$ , such that the more severe the FA the greater the perceived parental burden.

#### One Way ANOVA Group Comparisons

Due to large variability in parent trait anxiety scores, a further analysis was performed to examine the relationship between parent anxiety and major study variables. Specifically, to determine whether there were significant differences in child HRQoL and parental burden levels between families with certain anxiety cutoff scores, a one-way ANOVA was performed. Caregivers were categorized into a new variable that had low anxiety, moderate anxiety, and high anxiety categories by calculating two cut points that we used to create three near identical groups based on STAI trait

scores. The reason for dividing participants into three groups was to examine whether high anxiety levels, or both moderate and high anxiety levels, were predictive of impaired HRQoL as reported by both children and caregivers, and parental burden. Participants who sat under the first cut point were placed into the low anxiety group, those who sat between the first and second cut points were placed into the moderate anxiety group, and those above the second cut point were placed into the high anxiety group. Next, differences in HRQoL and parental burden were examined. Results indicated statistically significant differences between groups for parent reported child HRQoL ( $F(2,86) = 7.02$ ,  $p < .01$ ), child reported HRQoL ( $F(2,85) = 5.11$ ,  $p < .01$ ) and parental burden ( $F(2,141) = 9.66$ ,  $p < .01$ ). Conversely, no statistically significant differences were found between groups for child anxiety ( $F(2,68) = 1.14$ ,  $p = .326$ ). Please see Table 11 for results related to this analysis.

These aforementioned results met the assumption of homogeneity of variances, but group sizes were unequal, therefore, a Games-Howell post hoc test was performed to identify where differences occurred between the anxiety groups. Post hoc testing revealed statistically significant differences in parent reported child HRQoL for low ( $82.17 \pm 17.56$ ) and high ( $65.36 \pm 13.42$ ) anxiety groups, but not for medium and high anxiety groups ( $p = .18$ ) or low and medium ( $72.58 \pm 17.18$ ) groups ( $p = .18$ ). These results were repeated for child reported HRQoL with significant differences between low ( $81.43 \pm 14.51$ ) and high ( $68.70 \pm 13.29$ ) groups, but not for low and medium ( $74.34 \pm 15.34$ ) groups ( $p = .14$ ) and medium and high groups ( $p = .31$ ). Total parental burden was significantly greater for those in low ( $39.02 \pm 22.63$ ) and high ( $61.67 \pm 23.96$ ) anxiety groups ( $p = .000$ ) and medium ( $49.81 \pm 24.77$ ) to high groups ( $p = .05$ ), but not low and medium groups ( $p = .06$ ).

## Discussion

The present investigation was designed to examine the relationship between disease severity, anxiety, parental burden, and HRQoL in families who have a child diagnosed with FA. Specifically, it was hypothesized that children with FA would report significantly poorer HRQoL than their healthy counterparts. It was also expected that children with multiple allergies would report lower levels of HRQoL compared to children in the sample with just one or two allergies. Similarly, it was hypothesized that the child's illness severity would impact their overall HRQoL. Finally, it was hypothesized that both parent anxiety and parental burden would moderate the relationship between FA severity and child HRQoL, as reported by children and their caregivers.

The present study revealed some unexpected findings. For example, having multiple FAs did not predict child HRQoL, as reported by both children and their parents. A child's severity also did not predict child HRQoL as reported by children, and neither parent anxiety nor parental burden moderated the relationship between FA severity and child HRQoL. However, a number of significant findings did result from this study. Specifically, the finding that child HRQoL (i.e., parent proxy-report, child self-report) for children with FA, was significantly poorer than established healthy norms supported the hypothesis for the current investigation. In addition, as hypothesized, FA severity predicted lower child HRQoL scores as reported by parents, as well as child anxiety and parental burden.

### *Child Health-Related Quality of Life*

This study confirms previous findings that FA has a significant impact on both child and parent-reported child HRQoL (Avery et al., 2003; Bollinger, 2006; Cummings et al., 2010). This is a particularly important finding, as this is the first study with a New Zealand sample that demonstrates the impact FA has on a child's psychological, physical, social, and school functioning. Specifically,



the present study found children reported HRQoL levels that were significantly lower than their healthy counterparts, which included both total scores and all subscale scores of the PedsQL™ Generic Core Scales. This finding is similar to research that examined HRQoL among children with FA, among a non-New Zealand sample (Cummings et al., 2010; King et al., 2009). Similarly, this finding was bolstered by the fact that parents also reported their child's HRQoL as significantly poorer overall. However, parents reported significantly lower levels of HRQoL for only emotional, social, and psychosocial domains, which is consistent with previous research (Cummings et al., 2010; Roy et al., 2011; Valentine & Knibb, 2011).

As previously mentioned, the emotional domain of child HRQoL were reported as particularly impacted by both children and parents in the present sample, and significantly worse than scores reported for norm populations. This finding is in keeping with another study of children with FA (King et al., 2009). Given questions on the emotional domain of HRQoL involve fear, sadness, anger and worries, this finding is unsurprising. Children with FA may struggle with fear about a repeat of an allergic reaction they have previously experienced, and may feel traumatised by needing an injection of epinephrine. They may often worry about what might happen to them if they get exposed to an allergen unintentionally, or as part of clinical food challenges, which they may have failed in the past. These children may also feel sadness or anger when they miss out on parties and social occasion due to their FA, or have to take special food and miss out on eating items such as birthday cake.

As well as emotional domains of HRQoL, social domains were also particularly affected in the present sample as reported by both children and parents, and has also been reported previously (Cummings et al., 2010; King et al., 2009). Items that make up this domain revolve around peer relationships, teasing, and being able to do things other children do. It is possible that some parents have informed children who play with other children who have FA, especially nut allergies which tend to be associated with anaphylaxis, to take great care when playing with that child, which could be resulting in the children with FA being excluded. Furthermore, it is possible children who have

comorbid conditions such as asthma and eczema may be teased over these conditions, especially if the effects on their skin are highly visible. A growing body of literature exists that focuses on FA-related bullying, and this research reveals the impact bullying can have on the HRQoL of a child with FA (Lieberman et al., 2010; Shemesh et al., 2013; Torabi et al., 2016).

The finding that children rated their HRQoL as universally lower than healthy controls is very important in gaining an understanding of how children with FA in New Zealand are being affected by this condition. Specifically, tiredness is a feature of the physical domain in child HRQoL, which was reported by children as significantly worse than their peers. It is possible that children in the present sample may feel more tired than their peers for a number of reasons: their bodies may be busy fighting constant allergic reactions, and given the high frequency of children who reported previous history of anaphylaxis, these reactions likely involve a number of body systems, and will consequently take some time to recover from fully. Also, children in the present study were commonly allergic to many foods with 66% of the sample allergic to four or more foods. Consequently, these children may be on heavily restricted diets which could possibly be a cause of fatigue.

### *Multiple Allergies*

Perhaps the most interesting finding was that despite the vast majority of children in the present sample having multiple allergies, this was not significantly related to scores for child HRQoL as reported by both children and their caregivers. Similarly, multiple allergies were not a significant predictor of parent anxiety. This confirms previous, but counter-intuitive, findings that multiple allergies are not related to impaired HRQoL as reported by both children with FA and their parents, nor are they related to parent's anxiety (Cummings et al., 2010; King et al., 2009). Given that parent's anxiety was generally high, and children's HRQoL was generally low, this finding suggests that factors other than avoidance of certain foods may be creating stress and anxiety in families with FA. It is possible that multiple allergies in isolation is not a major stressor, but when this is added to other allergic features such as comorbid conditions and reaction severity and frequency, an effect on

HRQoL will be felt. A potential limitation was that very few children in the present study actually had just one allergy (10.4%) to compare to, therefore much larger studies in a New Zealand population, or studies which capture children with less allergies, would help confirm this finding.

Although multiple allergies were not associated with reports of child HRQoL, the number of allergies was, however, significantly related to both child anxiety and parent burden. This is inconsistent with previous research showing no significant relationship between multiple allergies and child anxiety (King et al., 2009) but corresponds with research reporting increased burden in parents of children with multiple allergies (Allen et al., 2015; Fathi et al., 2016). One explanation is that avoiding a lot of foods due to high numbers of allergens is particularly problematic in New Zealand populations. Because it is a very small country, commercially produced products that are free from allergens are very new to the food market, and development is still in its infancy. Consequently, there is little variety of these products and they are difficult to source and are very expensive. Eating out is particularly difficult with very few outlets specialising in products suitable for children with FA. For older children who want to go to malls and other places teenagers tend to gather, the unavailability of suitable food adds another layer of anxiety. They are faced with going hungry until they can get safe food at home, or bringing food from home, which may be a source of embarrassment for older children.

Lack of resourcing due to the small size of New Zealand is another potential source of anxiety for children with FA. Only a few larger cities have dedicated allergy specialists, meaning children need to travel long distances to get to a source of high quality allergy advice. This likely means majority of allergy care is passed over to General Practitioners (GPs), who may be overly conservative due to wanting to reduce as much risk as possible. Allergy specialists may have different views to GPs resulting in conflicting advice being given to children with their caregivers. Further, due to the lack of resourcing, families may turn to online support groups for further guidance, which while it does provide an important level of support, may complicate matters further by adding conflicting

advice. This conflict may be a source of increased anxiety for children trying to learn how to manage their condition safely.

Intuitively this finding makes sense in that items on the burden scale involve daily challenges associated with parenting a child with FA, such as cooking meals, leaving children with others and social restrictions, which would likely be impacted more if the number of foods needing to be avoided was higher. For example, if a child had one allergy such as a fish or shellfish allergy, cooking meals and buying food is relatively simple. However, well over half of the children in the study had four or more allergies so it is easy to imagine how difficult life becomes when parents need to check ingredients and cook meals without foods such as wheat, dairy and egg as well as fish. It is also easy to see why children with multiple allergies might have higher levels of anxiety. These children have likely experienced more allergic reactions than those with one or two allergies, and each time a young child experiences a reaction to a new food, they may end up with a negative association to that experience. As these experiences increase over time as foods are being introduced, they may begin to fear the introduction of a new food generally. These fears may generalise to other parts of their life, such as mealtimes, eating at school, and being around others who are eating, such as at social events.

### *Food Allergy Severity*

The present examination of FA severity yielded mixed results. In line with the study hypothesis, higher scores on FA severity predicted poorer ratings of child HRQoL as reported by parents. This is in keeping with previous research identifying that FA severity predicts poorer parent reported child HRQoL (Chow et al., 2015) but contrasts with studies concluding FA severity does not predict poorer child HRQoL as reported by parents (Marklund et al., 2006). Although FA severity predicted poorer ratings of child HRQoL as reported by parents, this significant finding was not replicated for child reported HRQoL. This parallels findings by Cummings and colleagues (2010) who also found FA severity was unrelated to children's own reports of their HRQoL. Although these findings may suggest parents are more inclined to rate the impact of disease severity on child HRQoL

worse than children themselves, and this has been noted previously (King et al., 2009), another interpretation is that caregivers may actually have a more realistic understanding of the impact FA severity has on their child's HRQoL. For example, children may have limited knowledge and memory of severe reactions, as doctors and parents may have chosen to keep many details from them as a means of protection from trauma. If considerable time has passed since a severe reaction, children may not remember many of the details whereas parents may recall these times, and their child's fears at the time vividly, which may affect the way they rate their child's HRQoL.

### *Anxiety*

The finding that caregivers of FA children in the present sample self-reported higher anxiety than published norms from healthy populations is in line with previous studies (King et al., 2009; Klinnert et al., 2014). The fact that levels of parent anxiety in the present study as measured by the STAI were in keeping with other studies of families with FA (King et al., 2009) or even higher than that reported in other FA studies (Lau et al., 2014; Zijlstra et al., 2010) suggests that parents of New Zealand children with FA are experiencing especially heightened anxiety related to their child's condition. This finding warrants further investigation, given the impact, high levels of anxiety are having on the caregiver, as well as the potential impact this may have on the child's functioning. For example, it has been suggested that anxiety may be a protective factor in families with FA (Warren et al., 2016). It is possible that heightened anxiety may translate into appropriate vigilance, such as constant ingredient checking and taking care to avoid cross contamination. However, it is important to consider parents of children with FA may be modeling maladaptive anxious responses for their child, especially during times of heightened stress such as mid-allergic reaction or during clinical testing for allergy. The present study showed that parent anxiety was indeed predictive of child anxiety, suggesting that parents may in fact be "passing on" their anxiety via these mechanisms. It is unclear whether child anxiety in the present sample stemmed from direct fear in their perception of being able to manage their allergy or a more general anxiety about the condition that may be fueled by

heightened anxiety in immediate family members. Regardless, further research in this particular area is clearly needed to better understand the relationship between parent and child anxiety among families with a child diagnosed as food allergic.

Because parent anxiety has been found to be associated with child HRQoL as highlighted in the literature review, the present study set out to ascertain whether parent anxiety would moderate the relationship between FA severity and child HRQoL. It was hypothesized that as FA severity increased, higher levels of anxiety would negatively impact child HRQoL. Contrary to the study hypotheses, parental anxiety was not found to moderate this relationship for either child self-report nor parent proxy-reported child HRQoL. These results suggest that the relationship between severity and both child and parent reports of child HRQoL were no stronger or weaker among children whose parents are challenged by feelings of anxiety. While there are several potential explanation for the lack of findings in this area, one might be that parent anxiety is indeed a protective factor. At the very least, it is important to consider how the measures used in this study, while certainly psychometrically robust and considered a widely accepted measure of anxiety, did not distinguish between “general anxiety” and “food allergy-related anxiety”. To better understand potential moderating effects of parent anxiety on the relationship between FA severity and child HRQoL, this methodological issue may need to be addressed. Specifically, it can be seen as an important next step to develop and validate measures that capture the idiosyncrasies of the anxiety experience of parents caring for children with FA.

### *Parental Burden*

Consistent with previous literature reporting that FA is associated with a great sense of parental burden (Allen et al., 2015; Cohen et al., 2004) the present study reports even higher parental burden than similar FA studies (Allen et al., 2015; Cohen et al., 2004; Leung et al., 2009; Warren et al., 2015). Although this investigation did not evaluate the statistical significance of those differences, this finding is certainly intuitive. This study also expands the emerging FA literature by showing FA

severity is a predictor of parental burden (Warren et al., 2015). The study analyses also demonstrate how parents with high anxiety feel a deeper sense of burden than do those parents with lower levels of anxiety. Taken together, these results imply that, for parents, the challenges of caring for a child with FA may lie in the day-to-day burden of FA care, such as preparing safe meals and checking ingredient lists. At the same time, relaxing activities which may counter this sense of burden, such as going out for meals and taking a holiday, can be especially difficult for families with FA. This may also suggest that parents with anxiety that persists over time, such as that measured in this study, may be overwhelmed by feelings of worry and fear about the present and the future, which make the everyday allergy tasks feel even more burdensome.

Based on the emerging literature showing the burden in families with FA outlined in the literature review, the present study set out to ascertain whether that sense of parental burden would moderate the relationship between FA severity and child HRQoL. It was hypothesised that those parents who had children with higher levels of disease severity, would also show evidence of lower levels of HRQoL if they perceived higher levels of FA related burden. Contrary to study hypotheses, parental burden was not found to moderate the relationship between the FA severity and child reported HRQoL, nor was it found to moderate the relationship between FA severity and parent reported child HRQoL. These results suggest that the relationship between severity and both child and parent reports of child HRQoL were no stronger or weaker among children whose parents felt a great sense of burden related to caring for a child with FA. The reasons for this finding are unclear. One explanation may be that although parents are perceiving a greater level of burden, they are not expressing this in a way that is perceivable to their children. Thus, the child's HRQoL may be relatively unaffected. Similarly, it may be that parents who perceive a higher amount of FA-related burden are doing more, in terms of managing their child's illness, which could have a positive impact on their HRQoL in specific areas. For example, it may be that parents are "carrying" the stress and difficulties of managing their child's FA for the child. However, given that FA severity was

predictive of parent reported impaired child HRQoL, it is possible parents are unaware of the way they are taking on the burden, and may be acting in more subconscious ways.

### *The Effect of Burden and Anxiety on Child Health-Related Quality of Life*

Results from regression analyses indicate that the poorer child HRQoL reported by parents was significantly related to the child's reports of anxiety and how much burden the parents perceived related to their child's FA. These results also suggest that children's own reports of HRQoL are also related to their perceived anxiety and the burden the parents perceive to have. This significant link between child anxiety and HRQoL has previously been identified (Roy & Roberts, 2011). Contrary to the aforementioned postulation that children are not perceiving their parent's burden in certain ways, it is possible that children are detecting the burden their parents are feeling resulting from their own FA in specific ways. For example, the constant vigilance required in checking all labels and ingredients, and having to take food with them everywhere, may result in a higher level on anxiety for children with FA. This constant vigilance could be both increasing children's own anxiety and contributing to poorer HRQoL overall.

### *Strengths of the study*

One of the major strengths of this study is that it utilised both parent proxy-report and child self-report of child HRQoL. As discussed in the literature review, this is rare in FA research to date, where most studies have chosen either child or parent reports (e.g., Chow et al., 2015; Shemesh et al., 2013; Valentine & Knibb, 2011). Consequently, the results from the current investigation may help provide a more complete and accurate picture of child HRQoL for children diagnosed with FA. Specifically, the methods used in the current study allow for a comparison of HRQoL scores between the child and their parent, which can be seen as strength. Intuitively it would seem likely that parents might rate their children's HRQoL as worse than children themselves due to the role caregivers of children with FA adopt in terms of helping to manage the illness, such as physical allergy care like



continually applying creams. However, the results from this study showed this was not the case, given both children and parents gave very similar ratings of child HRQoL overall.

Another major strength of the study was that it represents the first study of its kind in that it included participants from New Zealand. Additionally, the relatively large sample size ( $N=154$ ) is higher than many other FA studies from larger countries, such as the United Kingdom and the United States (Allen et al., 2015; Bollinger et al., 2006; Cortes et al., 2018; Cummings et al., 2010; Lau et al., 2014; Pinczower et al., 2103). Consequently, the results represent a large cross-section of the actual population of children with FA in the country of New Zealand.

#### *Limitations of the study and directions for future research*

A number of study limitations should be considered. Although the majority of FA studies have recruited by social media and allergy clinics, as done in the present study (Springston et al., 2010; Valentine & Knibb, 2011; Williams & Hankey, 2016), a proportion of FA studies have recruited participants exclusively from allergy clinics (Lau et al., 2014; LeBovidge, Strauch, Kalish & Schneider, 2009; Mizuno, Ohya, Nagao, DunnGalvin & Fujisawa, 2016). Consequently, the current investigation relied on allergy confirmation by the child's caregivers rather than it being verified by a medical professional. As noted in the results, 98.7% of the sample reported that their child's allergy had been diagnosed by skin prick or blood tests, which is the clinical testing standard used by allergy specialists (Sampson, 1999), or by biopsy for children with CD.

Another limitation for the present study was that the anxiety scale used for children is recommended for children from eight years of age. Consequently, a number of children in the present sample were unable to complete measures of anxiety due to their age. Despite this fact, the relatively high mean age of participants in the current study ( $M=7.11$  years), still allowed for 70 completed anxiety forms for child participants, which is similar to or higher than other studies that have

measured child reported anxiety (Herbert & Dahlquist, 2008; LeBovidge et al., 2009; Roy & Roberts, 2011).

Another limitation of the present study, which can be seen as a limitation for this area of investigation, is the lack of consensus over how to measure FA severity. The current investigation utilized a method used by other researchers that have summed a range of allergy variables, such as frequency of anaphylaxis, number of symptoms experienced, and number of foods the child is allergic to (Chow et al., 2015). Others have used a dichotomous variable which separates those who have experienced anaphylaxis and those who have not (Allen et al., 2015). One study used type and number of symptoms to determine FA severity (Cortes et al., 2018), and others have graded anaphylaxis into five levels (Sampson, 2003; Wassenberg et al., 2012). Others have had parents rate the severity into four groups (Valentine & Knibb, 2011). Clearly, a universal standard for estimating the severity of a child's FA is warranted.

Additionally, similar to previous investigations, the children in the present sample appear to be at the severe end of FA, which may be considered another limitation. As previously stated, nearly half of the sample had experienced anaphylaxis, which has been noted previously (Cohen et al., 2004; Lau et al., 2014; Springston et al., 2010), but does not align with general prevalence rates for anaphylaxis in the general allergy population (Lieberman et al., 2006). Furthermore, the children in the sample had more allergies than reported in other FA studies (Bollinger et al., 2006; Chow et al., 2015). Future research with a larger sample size and representation from a full range of children with FA, including those with a history of less severe reactions, and single allergies, would help ascertain if the results are generalisable to the full population of children with FA.

The cross-sectional design of the present study can also be seen as a potential limitation. Although the results identified a relationship between anxiety, parental burden and HRQoL in children with FA, we cannot determine whether FA specifically *caused* the high rates of anxiety, burden and impaired HRQoL. Future research using longitudinal studies of children with FA and their caregivers

would help make causal inferences about the effect anxiety and parental burden has on the relationship between FA and HRQoL.

### *Implications for clinical practice and research*

These results of the current study have both practical and empirical implications. Although the results suggest some children and parents of children with FA may have healthy and adaptive levels of overall functioning, the high rates of anxiety, parental burden and impaired HRQoL generally suggest clinicians working with these families need to be ready to identify families experiencing challenging psychological ramifications of FA, and be prepared to refer these families to appropriate services. Service providers should consider the implementation of screening protocols to identify families that may be experiencing heightened anxiety. In cases where a child or family member is identified, having resources that include referrals or specialists in CBT may provide help for these families (Boyle, 2017). Future research would do well to explore the efficacy of treatment protocols specifically designed to address the difficulties experienced by the allergy population further. Tailored interventions that target those difficulties, for both children with FA and their immediate family who may also be experiencing problems arising from their FA, could help improve the well-being of those families.

Another implication arising from the results is that educators may be able to provide support to parents feeling anxiety relating to their child's FA. This is important because educators are likely to see, and engage with, parents more often than do clinical specialists. An understanding of the potential challenges and anxieties in both children with FA and their parents may help foster support for these families. The research also highlights the impact FA has on a child with FAs ability to engage in regular social activities, which is important for educators to understand. A creative understanding about how best to include children with FA in social events, whilst removing the stigma and negative attitudes towards FA may be helpful for these families.

## *Conclusion*

In summary, this study highlights the significant relationships between parent characteristics, such as parental burden and anxiety, with child HRQoL in children with FA. It is clear FA can affect both children and their caregivers in both physical and psychological ways. There was no evidence from our results that multiple allergies increase impairments in HRQoL in children with FA but mixed evidence about the effect FA severity has on child and parent reported child HRQoL. Caregivers of children with FA who are experiencing anxiety, fear and overwhelming worry should be encouraged to seek help from an appropriate practitioner, as should parents of children exhibiting fearful responses which seem worrying. CBT, with psychoeducation tailored to FA, may help reduce the burden of FA for both children and parents of children with FA. Allergy specialists should be aware of the impact FA has on psychological outcomes in families with FA, and refer families for support if necessary.

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Table 1:

*Descriptive Data of Demographic Variables*

| Variable        | <i>n</i> | %    |
|-----------------|----------|------|
| Gender          |          |      |
| Male            | 79       | 51.4 |
| Female          | 75       | 48.6 |
| Relationship    |          |      |
| Mother          | 151      | 98.1 |
| Father          | 3        | 1.9  |
| Family Income   |          |      |
| 0-25,000        | 1        | 0.6  |
| 25,001-40,000   | 8        | 5.2  |
| 40,001-70,000   | 13       | 8.4  |
| 70,001-99,999   | 41       | 26.6 |
| 100,000-150,000 | 46       | 29.9 |
| 150,000 +       | 40       | 26.0 |
| Age             |          |      |
| 0-23 months     | 10       | 6.5  |
| 2-4             | 49       | 31.8 |
| 5-7             | 27       | 24.0 |
| 8-12            | 46       | 29.9 |
| 13-18           | 22       | 14.3 |

Table 2:

*Descriptive Data of Food Allergy Variables as Reported by Parents*

| Variable                | <i>n</i> | %    |
|-------------------------|----------|------|
| Carry Epipen            |          |      |
| Yes                     | 85       | 55.2 |
| No                      | 69       | 44.8 |
| Food Allergies          |          |      |
| Cows Milk               | 88       | 57.1 |
| Egg                     | 84       | 54.5 |
| Peanut                  | 81       | 52.6 |
| Treenuts                | 69       | 44.8 |
| Wheat                   | 17       | 11.1 |
| Soy                     | 16       | 10.4 |
| Sesame                  | 13       | 8.4  |
| Symptoms                |          |      |
| Hives                   | 117      | 76.0 |
| Itchiness               | 115      | 74.7 |
| Rash                    | 114      | 74.0 |
| Stomach upset           | 103      | 66.9 |
| Vomiting                | 96       | 62.3 |
| Lip/tongue swelling     | 75       | 48.7 |
| Wheeze                  | 70       | 45.5 |
| Breathing Difficulty    | 64       | 41.6 |
| Throat restriction      | 50       | 32.5 |
| Coeliac Disease         | 37       | 24.0 |
| Allergic Disease        |          |      |
| Eczema                  | 104      | 67.5 |
| Asthma                  | 80       | 51.9 |
| Worst Allergic Reaction |          |      |
| Mild-Moderate           | 86       | 55.8 |
| Severe (Anaphylaxis)    | 68       | 44.2 |
| Number of foods avoided |          |      |
| 1                       | 16       | 10.4 |
| 2-3                     | 37       | 24   |
| 4 or more               | 101      | 65.6 |

Table 3:

*Descriptive Statistics of Primary Variables of Interest*

| Variable                      | Mean (SD)    |
|-------------------------------|--------------|
| PedsQL™ Generic Core Scales   |              |
| Parent Proxy-Report           | 74.64(17.39) |
| Child Self-Report             | 75.38(15.02) |
| State Trait Anxiety Inventory |              |
| Adult Trait                   | 40.08(10.38) |
| Adult State                   | 37.03(11.32) |
| State Trait Anxiety Inventory |              |
| Child Trait                   | 46.06(8.37)  |
| Child State                   | 30.68(6.90)  |
| FAQL-PB                       | 2.92(1.47)   |



Table 4

*Bivariate Correlations for Primary Variables of Interest*

| Variables              | 1      | 2      | 3      | 4      | 5      | 6      | 7    | 8    | 9   |
|------------------------|--------|--------|--------|--------|--------|--------|------|------|-----|
| 1.FAQL-PB              | -      |        |        |        |        |        |      |      |     |
| 2.Parent Trait Anxiety | .57**  | -      |        |        |        |        |      |      |     |
| 3.Parent State Anxiety | .43**  | .75**  | -      |        |        |        |      |      |     |
| 4.Parent Proxy HRQoL   | .13    | -.37** | -.55** | -      |        |        |      |      |     |
| 5.Child HRQoL          | -.34** | -.37** | -.48** | .75**  | -      |        |      |      |     |
| 6.Child Trait Anxiety  | .34**  | .42**  | .40**  | -.61** | -.78** | -      |      |      |     |
| 7.Child State Anxiety  | -.62** | .24    | .12    | -.36** | -.45** | -.60** | -    |      |     |
| 8.Illness Severity     | .22**  | -.00   | -.40   | -.21*  | -.13   | .26*   | .15  | -    |     |
| 9.Comorbid Conditions  | .72    | -.06   | -.40   | -.19   | -.25** | .35**  | .25* | .31* | -   |
| 10.Foods Avoided       | .16    | .03    | -.07   | -.07   | -.06   | .16    | .13  | .71* | .08 |

*Note.* Higher scores on the PedsQL™ indicate *better* quality of life, whereas higher scores on the FAQL-PB indicate *poorer* quality of life. Inverse correlations between the two measures, therefore, indicate consistent reporting of quality of life on both measures.

\* $p < .05$ , \*\* $p < .01$

FAQL-PB=Food Allergy Quality of Life-Parental Burden Scale

Table 5

*PedsQL™ versus Healthy Control Norms*

|                       | FA Sample     | Healthy Controls | <i>T</i> Score |
|-----------------------|---------------|------------------|----------------|
| Child Reported HRQoL  |               |                  |                |
| PedsQL: Total         | 75.38 (15.02) | 82.87 (13.16)    | 4.83***        |
| Peds QL: Physical     | 82.50 (15.24) | 86.86 (13.88)    | 2.77*          |
| PedsQL: Emotional     | 65.03 (21.04) | 78.21 (18.64)    | 6.07***        |
| PedsQL: Social        | 76.00 (20.71) | 84.04 (17.43)    | 3.76**         |
| PedsQL: School        | 73.72 (18.55) | 79.92 (16.93)    | 3.24*          |
| PedsQL: Psychosocial  | 71.58 (16.88) | 80.73 (14.70)    | 5.25***        |
| Parent Reported HRQoL |               |                  |                |
| PedsQL: Total         | 74.64 (17.39) | 81.34 (15.92)    | 3.76**         |
| Peds QL: Physical     | 81.84 (16.52) | 83.26 (19.98)    | 0.84           |
| PedsQL: Emotional     | 60.99 (24.01) | 80.28 (16.99)    | 7.85***        |
| PedsQL: Social        | 76.82 (22.11) | 82.15 (20.08)    | 2.35*          |
| PedsQL: School        | 74.58 (21.02) | 76.91 (20.16)    | 1.08           |
| PedsQL: Psychosocial  | 70.80 (19.88) | 80.22 (15.84)    | 4.63***        |

PedsQL: Pediatric Quality of Life Inventory

M: Mean Score

SD: Standard Deviation

\*: significant at  $p < .05$ \*\*: significant at  $p < .01$ \*\*\*: significant at  $p < .001$

Table 6

*Hierarchical Regression Examining Moderating Role of Parent Anxiety on Food Allergy Severity  
Predicting Child-Reported Health-Related Quality of Life*

| Variable Entered   | <i>B</i> | <i>SE(B)</i> | $\beta$ | <i>t</i> | <i>R</i> <sup>2</sup> |
|--------------------|----------|--------------|---------|----------|-----------------------|
| Step 1             |          |              |         |          | .04                   |
| Child Age          | .84      | .45          | .20     | 1.88     |                       |
| Step 2             |          |              |         |          | .13                   |
| Child Age          | .71      | .42          | .17     | 1.68     |                       |
| Parent Anxiety     | -.52     | .15          | -.35    | -3.54**  |                       |
| FA Severity        | -.18     | .18          | -.10    | -.97     |                       |
| Step 3             |          |              |         |          | .02                   |
| Child Age          | .67      | .42          | .16     | 1.61     |                       |
| Parent Anxiety     | -.55     | .15          | -.37    | -3.68**  |                       |
| FA Severity        | -.09     | .19          | -.05    | -.46     |                       |
| Severity x Anxiety | 2.03     | 1.53         | .14     | 1.33     |                       |

Parent Anxiety as measured by the State Trait Anxiety Inventory-Trait Scale.

\* $p < .001$ , \*\* $p < .01$ .

$R^2 = .04$  for Step 1; Adjusted  $R^2 = .03$  for Step 1;  $R^2 = .17$  for Step 2; Adjusted  $R^2 = .14$  for Step 2;  $R^2 = .19$  for Step 3; Adjusted  $R^2 = .15$  for Step 3;  $\Delta R^2 = .02$  for Step 3 ( $p > .05$ ).

Table 7

*Hierarchical Regression Examining Moderating Role of Parent Anxiety on Food Allergy Severity  
Predicting Parent-Reported Child Health-Related Quality of Life*

| Variable Entered   | <i>B</i> | <i>SE(B)</i> | $\beta$ | <i>t</i> | <i>R</i> <sup>2</sup> |
|--------------------|----------|--------------|---------|----------|-----------------------|
| Step 1             |          |              |         |          | .39                   |
| Family Income      | 2.95     | 1.59         | .20     | 1.86     |                       |
| Step 2             |          |              |         |          | .13                   |
| Family Income      | 2.20     | 1.51         | .15     | 1.46     |                       |
| Parent Anxiety     | -.57     | .18          | -.33    | -3.27**  |                       |
| FA Severity        | -.35     | .21          | -.17    | -1.67    |                       |
| Step 2             |          |              |         |          | .01                   |
| Family Income      | 2.00     | 1.52         | .13     | 1.31     |                       |
| Parent Anxiety     | -.61     | .18          | -.35    | -3.40**  |                       |
| FA Severity        | -.27     | .22          | -.13    | -1.22    |                       |
| Severity x Anxiety | 1.89     | 1.82         | .11     | 1.04     |                       |

Parent Anxiety as measured by the State Trait Anxiety Inventory-Trait Scale.

\* $p < .001$ , \*\* $p < .01$ .

$R^2 = .04$  for Step 1; Adjusted  $R^2 = .03$  for Step 1;  $R^2 = .17$  for Step 2; Adjusted  $R^2 = .14$  for Step 2;  $R^2 = .18$  for Step 3; Adjusted  $R^2 = .14$  for Step 3;  $\Delta R^2 = .01$  for Step 3 ( $p > .05$ ).

Table 8

*Hierarchical Regression Examining Moderating Role of Parental burden on Food Allergy Severity  
Predicting Child-Reported Health-Related Quality of Life*

| Variable Entered  | <i>B</i> | <i>SE(B)</i> | $\beta$ | <i>t</i> | <i>R</i> <sup>2</sup> |
|-------------------|----------|--------------|---------|----------|-----------------------|
| Step 1            |          |              |         |          | .04                   |
| Child Age         | .83      | .41          | .21     | 2.03*    |                       |
| Step 2            |          |              |         |          | .25                   |
| Child Age         | .33      | .37          | .08     | .89      |                       |
| Parental burden   | -.31     | .06          | -.50    | -5.40**  |                       |
| FA Severity       | -.05     | .16          | -.03    | -.30     |                       |
| Step 2            |          |              |         |          | .00                   |
| Child Age         | .36      | .37          | .09     | .97      |                       |
| Parental burden   | -.30     | .06          | -.49    | -5.09**  |                       |
| FA Severity       | -.27     | .22          | -.13    | -1.22    |                       |
| Severity x Burden | 1.28     | 1.70         | .07     | .75      |                       |

Parental burden as measured by the Food Allergy Quality of Life-Parental Burden Scale (FAQL-PB).

\* $p < .001$ , \*\* $p < .01$ .

$R^2 = .04$  for Step 1; Adjusted  $R^2 = .03$  for Step 1;  $R^2 = .29$  for Step 2; Adjusted  $R^2 = .26$  for Step 2;  $R^2 = .29$  for Step 3; Adjusted  $R^2 = .26$  for Step 3;  $\Delta R^2 = .00$  for Step 3 ( $p > .05$ ).

Table 9

*Hierarchical Regression Examining Moderating Role of Parental Burden on Food Allergy Severity  
Predicting Parent-Reported Child Health-Related Quality of Life*

| Variable Entered  | <i>B</i> | <i>SE(B)</i> | $\beta$ | <i>t</i> | <i>R</i> <sup>2</sup> |
|-------------------|----------|--------------|---------|----------|-----------------------|
| Step 1            |          |              |         |          | .05                   |
| Family Income     | 3.26     | 1.53         | .22     | 2.14*    |                       |
| Step 2            |          |              |         |          | .39                   |
| Family Income     | 2.74     | 1.24         | .18     | 2.21*    |                       |
| Parental burden   | -.41     | .06          | -.57    | -6.75**  |                       |
| FA Severity       | -.16     | .17          | -.10    | -.94     |                       |
| Step 2            |          |              |         |          | .39                   |
| Family Income     | 2.74     | 1.24         | .18     | 2.20*    |                       |
| Parental burden   | -.41     | .06          | -.57    | -6.34**  |                       |
| FA Severity       | -.17     | .18          | -.08    | -.94     |                       |
| Severity x Burden | .19      | 1.90         | .01     | .10      |                       |

Parental burden as measured by the Food Allergy Quality of Life Parental Burden Scale (FAQL-PB).

\* $p < .001$ , \*\* $p < .01$ .

$R^2 = .05$  for Step 1; Adjusted  $R^2 = .04$  for Step 1;  $R^2 = .39$  for Step 2; Adjusted  $R^2 = .37$  for Step 2;  $R^2 = .39$  for Step 3; Adjusted  $R^2 = .36$  for Step 3;  $\Delta R^2 = .00$  for Step 3 ( $p > .05$ ).

Table 10

*Regression Analyses between Food Allergy Severity and Major Study Variables*

| Variable              | <i>B</i> | (95% CI)    | <i>t</i> | p-value    | R Square | Adj. R Square |
|-----------------------|----------|-------------|----------|------------|----------|---------------|
| Self Reported HRQoL   | -.23     | (-.59-.13)  | -1.27    | <b>.00</b> | .06      | .04           |
| Parent Reported HRQoL | -.39     | (-.81-.02)  | -1.89    | <b>.02</b> | .08      | .06           |
| Parental burden       | .77      | (.28-1.26)  | 3.11     | <b>.00</b> | .18      | .16           |
| Parent Anxiety        | -.02     | (-.25-.21)  | -.16     | .87        | .05      | .04           |
| Child Anxiety         | -.29     | (-.50--.07) | -2.66    | <b>.01</b> | .15      | .11           |

Table 11

*Results of one way ANOVA by anxiety grouping (low, medium, high)*

| Dependent Variable    |                | Sum of Squares | df  | Mean Square | F    | Sig.   |
|-----------------------|----------------|----------------|-----|-------------|------|--------|
| Parent Reported HRQoL | Between Groups | 3792.25        | 2   | 1896.13     | 7.02 | .002** |
|                       | Within Groups  | 23240.12       | 86  | 270.23      |      |        |
|                       | Total          | 27032.37       | 88  |             |      |        |
| Child Reported HRQoL  | Between Groups | 2161.67        | 2   | 1080.83     | 5.11 | .008** |
|                       | Within Groups  | 17.993.66      | 85  | 211.69      |      |        |
|                       | Total          | 20155.33       | 87  |             |      |        |
| Child Anxiety         | Between Groups | 158.87         | 2   | 79.43       | 1.14 | .326   |
|                       | Within Groups  | 4740.91        | 68  | 69.72       |      |        |
|                       | Total          | 4899.78        | 70  |             |      |        |
| Parental burden       | Between Groups | 11041.16       | 2   | 5520.58     | 9.66 | .000** |
|                       | Within Groups  | 80597.33       | 141 | 571.61      |      |        |
|                       | Total          | 91638.49       | 143 |             |      |        |

\*\* The mean difference is significant at the .01 level



Figure 1: Anxiety as a Moderator of the Relationship between Food Allergy Severity and Child Health-Related Quality of Life

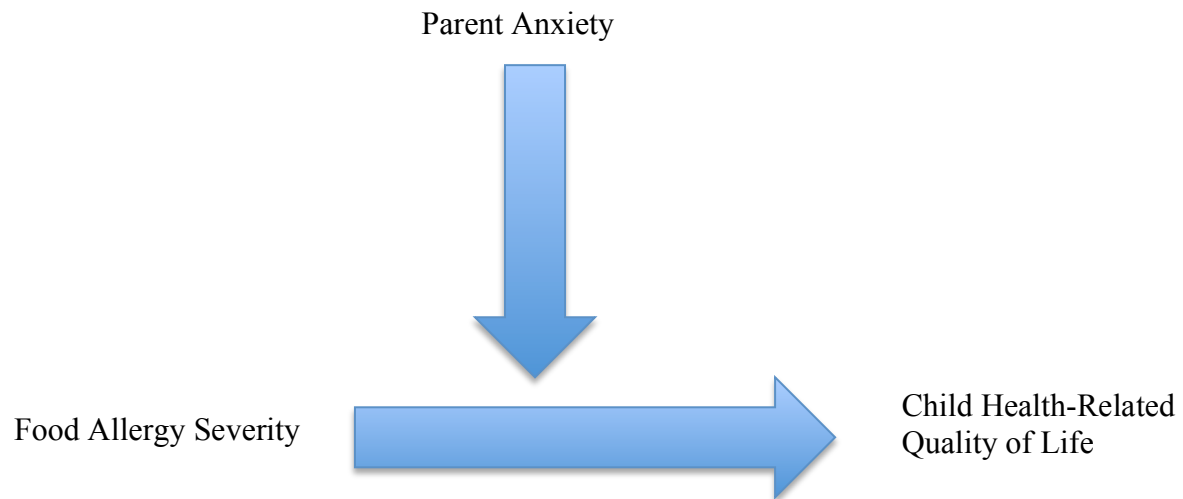
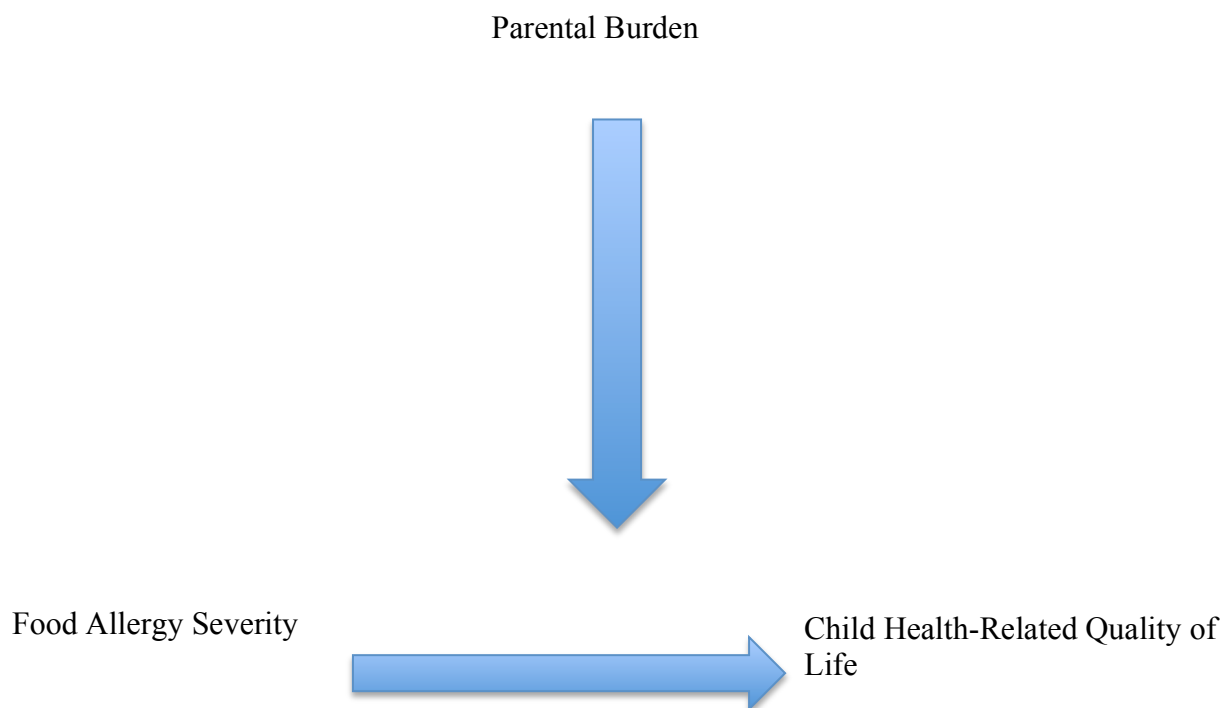
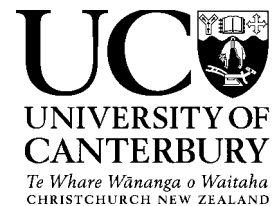


Figure 2: Parental Burden as a Moderator of the Relationship between Food Allergy Severity and Child Health-Related Quality of Life



## Appendices

### Appendix 1: Study Advertisement



## University of Canterbury Food Allergy Study

### Does your child have a medically diagnosed food allergy?

*(Note: this includes IgE-mediated immune reactions & other adverse immune reactions to foods e.g. coeliac disease)*

### Are you interested in contributing your experiences of living with Food Allergy to research looking at the impact of food allergy on New Zealand children and their families?

If your answer is yes to both questions above, please read on:

My name is Malena Penney and I am a Masters student at the University of Canterbury. My research is investigating the impact food allergy can have on families. Specifically, we are looking at parental anxiety associated with Food Allergy, parental burden associated with Food Allergy, and child quality of life. Ultimately, we are hoping that the results from this study will inform future efforts designed to provide needed support for families who have a child with Food Allergy.

\*Participants should have a child aged 0- 18 years of age who has been diagnosed with a food allergy by a doctor.

Study participants will be asked to complete questionnaires that will allow researchers to gain a better understanding of the impact Food Allergy can have on a family, particularly primary caregivers and the child with Food Allergy. These questionnaires will be mailed to you with return postage for returning them to ensure there is no monetary cost to you and are expected to take 20-30 minutes to complete.

**If you are interested in participating in this study, or would like to find out more about what will be involved, please email the primary researcher, Malena Penney at [mjp169@uclive.ac.nz](mailto:mjp169@uclive.ac.nz)**

If you don't have access to email, please feel free to call the primary supervisor, Michael Steele, PhD. on +64-3-36-92935 ext. 92935 and the information forms can be mailed to you.

Responding to this request will not obligate you to participate in this research.

This study has been approved by the Department of Child and Family Psychology, University of Canterbury.

If you have questions or concerns about this project feel free to contact either the primary researcher or her supervisor.

Primary researcher: Malena Penney  
Department of Child and Family Psychology, University of Canterbury  
Email: [mjp169@uclive.ac.nz](mailto:mjp169@uclive.ac.nz)

Primary supervisor: Dr. Michael Steele  
Department of Child and Family Psychology, University of Canterbury  
Email: [michael.steele@canterbury.ac.nz](mailto:michael.steele@canterbury.ac.nz) Telephone: 03-369 2935 ext. 92935

## Appendix 2: Instruction Sheet

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Department of Child and Family Psychology  
 Telephone: 0211792708  
 Email: [mjp169@uclive.ac.nz](mailto:mjp169@uclive.ac.nz)  
 1 August 2018

### **The role of Parent Perception of Burden on Child Health Related Quality of Life: Examining Functioning among Children with Food Allergy**

#### Instruction Sheet for study participants

My name is Malena Penney and I am a Masters student at the University of Canterbury. My research is investigating the impact Food Allergy has on families who have a child with a Food Allergy.

In the envelope, you should find:

1. Pediatric Quality of Life family information form, to be completed by the primary caregiver.
2. Pediatric Quality of Life Inventory Generic Core Scales-Child Self-Report Form, to be completed by your child if they are over the age of five or by the primary caregiver if aged under five
3. State-Trait Anxiety Inventory (child), to be completed by your child, if they are eight years of age or older. If your child is younger than eight, please leave this form blank.
4. State-Trait Anxiety (adult) to be completed by the primary caregiver
5. FAQL-PB (Food Allergy Quality of Life-Parental Burden) form, to be completed by the primary caregiver
6. Return envelope complete with postage

These forms should take about 20-30 minutes to complete. Participation is voluntary and you have the right to withdraw at any stage without penalty. Please ensure you respect your child's wishes regarding their involvement in this study by explaining to them that participation is voluntary and that nobody will be upset with them if they decide not to participate. You may ask for your raw data to be returned to you or destroyed at any point. If you withdraw, I will remove information

relating to you. Please note, for your security any identifying information will be kept separate from the data collection and will be backed up on University of Canterbury servers and stored for a period of five years.

Who to complete the study for?

If by chance you have more than one child with Food Allergy, please complete the forms for the child who you consider to have the most severe symptoms.

If you have any concerns or questions about the study, please contact either:

Primary researcher: Malena Penney  
Department of Child and Family Psychology, University of Canterbury  
Email: [mjp169@uclive.ac.nz](mailto:mjp169@uclive.ac.nz) Telephone: 021 1792708

Primary supervisor: Dr. Michael Steele  
Department of Child and Family Psychology, University of Canterbury  
Email: [michael.steele@canterbury.ac.nz](mailto:michael.steele@canterbury.ac.nz) Telephone: 02108043218

It is possible that some questions asked in this study may cause you or your child some distress. If you do experience stress or emotional distress when completing these questionnaires, and feel the need for support, please contact one of the following support agencies as soon as possible:

Youthline 0800 376 633  
The Depression Helpline 0800 111 757  
Healthline 0800 611 116  
Lifeline 0800 543 354

If you are seriously concerned about your own, or your child's immediate safety, Call 111 or take them to the Accident and Emergency Department at your nearest hospital. For further information on where to access Mental Health Services, please go to:

[www.health.govt.nz/your-health/services-and-support/health-care-services/mental-health-services](http://www.health.govt.nz/your-health/services-and-support/health-care-services/mental-health-services)

For services specific to Allergy, please contact Allergy New Zealand ([www.allergy.org.nz](http://www.allergy.org.nz)) to access a volunteer regional support coordinator who provide general information about allergy. This agency also organises support group meetings where you are able to meet others facing similar challenges.

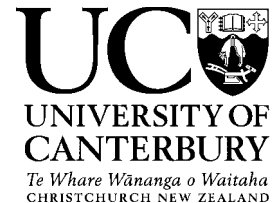
This project has been reviewed and approved by the University of Canterbury Human Ethics

Committee, and participants should address any complaints to The Chair, Human Ethics Committee,

University of Canterbury, Private Bag 4800, Christchurch ([human-ethics@canterbury.ac.nz](mailto:human-ethics@canterbury.ac.nz)).

### Appendix 3: Parent Consent Form

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Department of Child and Family Psychology  
 Telephone: 021 1792708  
 Email: [mjp169@uclive.ac.nz](mailto:mjp169@uclive.ac.nz)  
 1 May 2018

### **The role of Parent Perception of Burden on Child Health Related Quality of Life: Examining Functioning among Children with Food Allergy**

*My name is Malena Penney and I am a Masters student at the University of Canterbury. My Masters research will be investigating the impact Food Allergy has on families who have a child with a Food Allergy.*

If you choose to take part in this study, you and your child's involvement in this project will be completing measures of Quality of Life and anxiety as well as a Food Allergy-specific scale measuring parental burden. These 5 short measures will be mailed to you in one packet containing return postage and are expected to take approximately 30 minutes to complete.

Participation is voluntary and you have the right to withdraw at any stage without penalty. You may ask for your raw data to be returned to you or destroyed at any point. If you withdraw, I will remove information relating to you. However, once analysis of raw data starts on approximately the 1<sup>st</sup> of August, it will become increasingly difficult to remove the influence of your data on the results.

The results of the project may be published, but you may be assured of the complete confidentiality of data gathered in this investigation: your identity will not be made public. To ensure anonymity and confidentiality, any data will be stored securely in a locker in the Child and Family Psychology building on a password-protected flash drive, and any online documents will be stored on an IronKey flash drive with data encryption. A thesis is a public document and will be available through the UC Library.

Please indicate to the researcher on the consent form if you would like to receive a copy of the summary of results of the project.

The project is being carried out as a requirement for a Masters in Science (child and family psychology) by Malena Penney ([mjp169@uclive.ac.nz](mailto:mjp169@uclive.ac.nz)) under the supervision of Dr. Michael Steele, PhD who can be contacted at [michaelsteele@canterbury.ac.nz](mailto:michaelsteele@canterbury.ac.nz). He will be pleased to discuss any concerns you may have about participation in the project.

It is unlikely, but possible that some questions asked in this study may cause you or your child some distress. If you do experience stress or emotional distress when completing these questionnaires, and feel the need for support, please contact one of the following support agencies as soon as possible:

Youthline 0800 376 633  
 The Depression Helpline 0800 111 757  
 Healthline 0800 611 116  
 Lifeline 0800 543 354

If you are seriously concerned about your own, or your child's immediate safety, Call 111 or take them to the Accident and Emergency Department at your nearest hospital. For further information on where to access Mental Health Services, please go to: [www.health.govt.nz/your-health/services-and-support/health-care-services/mental-health-services](http://www.health.govt.nz/your-health/services-and-support/health-care-services/mental-health-services)

For services specific to Allergy, please contact Allergy New Zealand ([www.allergy.org.nz](http://www.allergy.org.nz)) to access a volunteer regional support coordinator who provide general information about allergy. This agency also organises support group meetings where you are able to meet others facing similar challenges.

This project has been reviewed and approved by the University of Canterbury Human Ethics Committee, and participants should address any complaints to The Chair, Human Ethics Committee, University of Canterbury, Private Bag 4800, Christchurch ([human-ethics@canterbury.ac.nz](mailto:human-ethics@canterbury.ac.nz)).

If you agree to participate in the study, you are asked to complete the consent form and return by email to Malena Penney at [mjp169@uclive.ac.nz](mailto:mjp169@uclive.ac.nz)



Department of Child and Family Psychology  
Telephone: 021 1792708

Email: [malena@penney.co.nz](mailto:malena@penney.co.nz)

Quality of life and anxiety with Food Allergy  
Consent Form for parents of children with medically diagnosed Food Allergy

- ☐ I have been given a full explanation of this project and have had the opportunity to ask questions.
- ☐ I understand what is required of me if I agree to take part in the research.
- ☐ I understand that participation is voluntary and I may withdraw at any time without penalty. Withdrawal of participation will also include the withdrawal of any information I have provided should this remain practically achievable.
- ☐ I understand that any information or opinions I provide will be kept confidential to the researcher and her supervisor, Dr. Michael Steele and that any published or reported results will not identify the participants. I understand that a thesis is a public document and will be available through the UC Library.
- ☐ I understand that all data collected for the study will be kept in locked and secure facilities and/or in password protected electronic form and will be destroyed after six years.
- ☐ I understand the risks associated with taking part and how they will be managed.
- ☐ I understand that I can contact the researcher, Malena Penney ([malena@penney.co.nz](mailto:malena@penney.co.nz)) or supervisor Dr. Michael Steele ([michael.steele@canterbury.ac.nz](mailto:michael.steele@canterbury.ac.nz)) for further information. If I have any complaints, I can contact the Chair of the University of Canterbury Human Ethics Committee, Private Bag 4800, Christchurch ([human-ethics@canterbury.ac.nz](mailto:human-ethics@canterbury.ac.nz))
- ☐ I would like a summary of the results of the project.
- ☐ By signing below, I agree to participate in this research project.

Name: \_\_\_\_\_ Signed: \_\_\_\_\_ Date: \_\_\_\_\_

Email address (*for report of findings if desired*): \_\_\_\_\_

## Appendix 4: Child Assent Form

**Children's Assent Form**

The project that Malena Penney wants to do about Food Allergies has been explained to me. I know I don't have to be a part of it if I don't want to and my parents won't be upset if I say no to taking part. If I have any questions I can ask my parents.

- I am happy to be part of the project and to complete some questions about my Food Allergies and my feelings and worries, so I have coloured in the happy face

**OR**

- I don't want to be part of the project or to answer these questions, so I have coloured in the sad face



My name: \_\_\_\_\_

## Appendix 5: Ethics Approval



### HUMAN ETHICS COMMITTEE

Secretary, Rebecca Robinson  
 Telephone: +64 03 369 4588, Extn 94588  
 Email: [human-ethics@canterbury.ac.nz](mailto:human-ethics@canterbury.ac.nz)

Ref: HEC 2018/63

3 August 2018

Malena Penney  
 Health Sciences  
 UNIVERSITY OF CANTERBURY

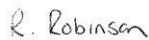
Dear Malena

The Human Ethics Committee advises that your research proposal “The Role of Parent Perception of Burden on Child Health Related Quality of Life: Examining Functioning Among Children with Food Allergy” has been considered and approved.

Please note that this approval is subject to the incorporation of the amendments you have provided in your emails of 19<sup>th</sup> and 31<sup>st</sup> July 2018.

Best wishes for your project.

Yours sincerely

pp. 

Professor Jane Maidment  
**Chair**  
*University of Canterbury Human Ethics Committee*

## Appendix 6: PedsQ™ Family Information Form

*Family Information Form*

|   |  |  |   |                         |               |
|---|--|--|---|-------------------------|---------------|
| <b>What is your relationship to this child (please check and/or circle)?</b><br><input type="checkbox"/> Mother, Step Mother, Foster Mother <input type="checkbox"/> Grandmother <input type="checkbox"/> Guardian<br><input type="checkbox"/> Father, Step Father, Foster Father <input type="checkbox"/> Grandfather <input type="checkbox"/> Other   |  |  |   |                         |               |
| <b>INFORMATION ABOUT THE CHILD</b>  |  |  |   |                         |               |
| Date of Birth (month/day/year):<br>/ /  |  | Do you have private medical insurance?<br><input type="checkbox"/> NO <input type="checkbox"/> YES |   | Age of child now: _____ |               |
| Child is:<br><input type="checkbox"/> male <input type="checkbox"/> female  |  |  |   |                         |               |
| Ethnic Group or Race of Child: <input type="checkbox"/> Māori <input type="checkbox"/> Pacific Island <input type="checkbox"/> NZ European <input type="checkbox"/> Asia <input type="checkbox"/> Other _____   |  |  |   |                         |               |
| <b>INFORMATION ABOUT MOTHER</b>   |  |  | <b>INFORMATION ABOUT FATHER</b>   |                         |               |
| Marital Status: <input type="checkbox"/> Single <input type="checkbox"/> Living with someone <input type="checkbox"/> Married <input type="checkbox"/> Divorced   |  |  | Marital Status: <input type="checkbox"/> Single <input type="checkbox"/> Living with someone <input type="checkbox"/> Married <input type="checkbox"/> Divorced |                         |               |
| <i>In the past 30 days, how many days have you missed from work due to your child's physical or mental health?</i> _____  |  |  |   |                         |               |
| <i>In the past 30 days, has your child's health interfered with...</i>  |  | Never  | Almost Never  | Sometimes               | Often         |
|   |  |  |   |                         | Almost Always |
| Your daily routine at work  |  | 0  | 1   | 2                       | 3             |
| Your ability to concentrate at work   |  | 0  | 1   | 2                       | 3             |
| Does your child have any siblings?<br><input type="checkbox"/> NO <input type="checkbox"/> YES  |  | IF YES... How many? _____<br>Do any of the siblings also have food allergies? _____                |   |                         |               |
| Who diagnosed your child's allergy?<br><input type="checkbox"/> GP <input type="checkbox"/> allergy specialist <input type="checkbox"/> other (please specify) _____  |  |  |   |                         |               |
| How the allergy diagnosed?<br><input type="checkbox"/> Skin prick testing <input type="checkbox"/> RAST testing <input type="checkbox"/> other blood test <input type="checkbox"/> other (please specify) _____   |  |  |   |                         |               |
| Has your child ever experienced anaphylaxis?<br><input type="checkbox"/> NO <input type="checkbox"/> YES  |  | If yes, how many times has this occurred? _____  |   |                         |               |
| How many foods does your child avoid due to allergy? _____  |  |  |   |                         |               |
| What types of symptoms has your child experienced when they have had an allergic reaction?<br><input type="checkbox"/> rash <input type="checkbox"/> hives/welts <input type="checkbox"/> vomiting <input type="checkbox"/> itchiness <input type="checkbox"/> upset stomach <input type="checkbox"/> wheezing  |  |  |   |                         |               |
| Does your child have medically diagnosed Food Allergy?<br><input type="checkbox"/> NO <input type="checkbox"/> YES  |  |  |   |                         |               |
|   |  | IF YES... When was the diagnosis? _____<br>IF YES... Age at diagnosis: _____                       |   |                         |               |
| <i>In the past 6 months, has your child...</i><br>Had a <b>chronic health condition</b> (defined as a physical or mental health condition that has lasted or is expected to last at least 6 months, and interferes with your child's activities)? <input type="checkbox"/> NO <input type="checkbox"/> YES  |  |  |   |                         |               |
|   |  | IF YES... What is the name of your child's chronic health condition? _____                         |   |                         |               |
| <i>In the past 12 months, relating to Food Allergy, (including asthma and skin conditions) has your child had...</i>  |  |  |   |                         |               |
| Any <b>OVERNIGHT VISITS</b> to the hospital?<br><input type="checkbox"/> NO <input type="checkbox"/> YES  |  | IF YES... How many times? _____<br>What was wrong? _____   |   |                         |               |
| Any <b>EMERGENCY ROOM/URGENT CARE</b> visits?<br><input type="checkbox"/> NO <input type="checkbox"/> YES   |  | IF YES... How many times? _____<br>What was wrong? _____   |   |                         |               |
| <i>In the past 30 days...</i><br>How many days did your child miss from school due to physical or mental health? _____<br>How many days was your child sick in bed or too ill to play? _____<br>How many days did your child need someone to care for him/her due to physical or mental health? _____<br>How many times did your child miss out on social events due to their food allergy? _____ |  |  |   |                         |               |
| <i>If you work outside of the home, please answer the following questions.</i>  |  |  |   |                         |               |

## Appendix 7: Food Allergy Quality of Life-Parental Burden Scale

**Food Allergy Quality of Life: Parental Burden Questionnaire**

1. If you and your family were planning a holiday/vacation, how much would your choice of vacation be limited by your child's food allergy?

|               |                         |                    |                      |                       |                |                     |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|
| 0-not limited | 1-hardly limited at all | 2-somewhat limited | 3-moderately limited | 4-quite a bit limited | 5-very limited | 6-extremely limited |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|

2. If you and your family were planning to go out to a restaurant, how much would your choice of a restaurant be limited by your child's food allergy?

|               |                         |                    |                      |                       |                |                     |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|
| 0-not limited | 1-hardly limited at all | 2-somewhat limited | 3-moderately limited | 4-quite a bit limited | 5-very limited | 6-extremely limited |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|

3. If you and your family were planning to participate in social activities with others involving food (e.g. parties, holiday etc) how limited would your ability to participate in social activities that involve food be because of your child's food allergy?

|               |                         |                    |                      |                       |                |                     |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|
| 0-not limited | 1-hardly limited at all | 2-somewhat limited | 3-moderately limited | 4-quite a bit limited | 5-very limited | 6-extremely limited |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|

4. In the past week, how troubled have you been by your need to spend extra time preparing meals (i.e. label-reading, extra time shopping, preparing extra meals, etc.) due to your child's allergy?

|               |                         |                    |                      |                       |                |                     |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|
| 0-not limited | 1-hardly limited at all | 2-somewhat limited | 3-moderately limited | 4-quite a bit limited | 5-very limited | 6-extremely limited |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|

5. In the past week, how troubled have you been about your need to take special precautions before going out of the home with your child because of their food allergy?

|               |                         |                    |                      |                       |                |                     |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|
| 0-not limited | 1-hardly limited at all | 2-somewhat limited | 3-moderately limited | 4-quite a bit limited | 5-very limited | 6-extremely limited |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|

6. In the past week, how troubled have you been by anxiety relating to your child's food allergy?

|               |                         |                    |                      |                       |                |                     |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|
| 0-not limited | 1-hardly limited at all | 2-somewhat limited | 3-moderately limited | 4-quite a bit limited | 5-very limited | 6-extremely limited |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|

7. In the past week, how troubled have you been that your child may not overcome their food allergy?

|               |                         |                    |                      |                       |                |                     |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|
| 0-not limited | 1-hardly limited at all | 2-somewhat limited | 3-moderately limited | 4-quite a bit limited | 5-very limited | 6-extremely limited |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|

8. In the past week, how troubled have you been by the possibility of, or actually leaving your child in the care of others because of their food allergy?

|               |                         |                    |                      |                       |                |                     |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|
| 0-not limited | 1-hardly limited at all | 2-somewhat limited | 3-moderately limited | 4-quite a bit limited | 5-very limited | 6-extremely limited |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|



9. In the past week, how troubled have you been by frustration over other's lack of appreciation for the seriousness of food allergy?

|               |                         |                    |                      |                       |                |                     |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|
| 0-not limited | 1-hardly limited at all | 2-somewhat limited | 3-moderately limited | 4-quite a bit limited | 5-very limited | 6-extremely limited |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|

10. In the past week, how troubled have you been by sadness regarding the burden your child carried because of their food allergy?

|               |                         |                    |                      |                       |                |                     |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|
| 0-not limited | 1-hardly limited at all | 2-somewhat limited | 3-moderately limited | 4-quite a bit limited | 5-very limited | 6-extremely limited |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|

11. In the past week, how troubled have you been about your child's attending school, camp, daycare or other group activity with children because of their food allergy?

|               |                         |                    |                      |                       |                |                     |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|
| 0-not limited | 1-hardly limited at all | 2-somewhat limited | 3-moderately limited | 4-quite a bit limited | 5-very limited | 6-extremely limited |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|

12. In the past week, how troubled have you been by your concerns for your child's health because of their food allergy?

|               |                         |                    |                      |                       |                |                     |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|
| 0-not limited | 1-hardly limited at all | 2-somewhat limited | 3-moderately limited | 4-quite a bit limited | 5-very limited | 6-extremely limited |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|

13. In the past week, how troubled have you been with the worry that you will not be able to help your child if they have an allergic reaction to food?

|               |                         |                    |                      |                       |                |                     |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|
| 0-not limited | 1-hardly limited at all | 2-somewhat limited | 3-moderately limited | 4-quite a bit limited | 5-very limited | 6-extremely limited |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|

14. In the past week, how troubled have you been with the worry that your child will not have a normal upbringing because of their food allergy?

|               |                         |                    |                      |                       |                |                     |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|
| 0-not limited | 1-hardly limited at all | 2-somewhat limited | 3-moderately limited | 4-quite a bit limited | 5-very limited | 6-extremely limited |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|

15. In the past week, how troubled have you been about concerns for your child's nutrition because of their food allergy?

|               |                         |                    |                      |                       |                |                     |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|
| 0-not limited | 1-hardly limited at all | 2-somewhat limited | 3-moderately limited | 4-quite a bit limited | 5-very limited | 6-extremely limited |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|

16. In the past week, how troubled have you been with issues concerning your child being near others while eating because of their food allergy?

|               |                         |                    |                      |                       |                |                     |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|
| 0-not limited | 1-hardly limited at all | 2-somewhat limited | 3-moderately limited | 4-quite a bit limited | 5-very limited | 6-extremely limited |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|

17. In the past week, how troubled have you been with being frightened by the thought that your child will have a food allergic reaction?

|               |                         |                    |                      |                       |                |                     |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|
| 0-not limited | 1-hardly limited at all | 2-somewhat limited | 3-moderately limited | 4-quite a bit limited | 5-very limited | 6-extremely limited |
|---------------|-------------------------|--------------------|----------------------|-----------------------|----------------|---------------------|

## Appendix 8: State Trait Anxiety Inventory (Adult Form)

### State Trait Anxiety Inventory (STAI) Sample Items

Due to copyright laws, only five sample items from the measure may be included in the present document. The scale asks for items such as these to be scored on a four-point scale.

1. I feel pleasant
2. I feel satisfied with myself
3. I wish I could be as happy as others seem to be
4. I feel like a failure
5. I have disturbing thoughts

## Appendix 9: PedsQL™ Generic Core Scales Sample Forms

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|           |             |
|-----------|-------------|
| ID# _____ | Date: _____ |
|-----------|-------------|

# PedsQL™

## Pediatric Quality of Life Inventory

Version 4.0

**CHILD REPORT** (ages 8-12)

**DIRECTIONS**

On the following page is a list of things that might be a problem for you. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.  
If you do not understand a question, please ask for help.



PedsQL 2

In the past **ONE month**, how much of a **problem** has this been for you ...

| <b>ABOUT MY HEALTH AND ACTIVITIES (problems with...)</b> | Never | Almost<br>Never | Some-<br>times | Often | Almost<br>Always |
|--|-------|-----------------|----------------|-------|------------------|
| 1. It is hard for me to walk more than one block         | 0     | 1               | 2              | 3     | 4                |
| 2. It is hard for me to run                              | 0     | 1               | 2              | 3     | 4                |
| 3. It is hard for me to do sports activity or exercise   | 0     | 1               | 2              | 3     | 4                |
| 4. It is hard for me to lift something heavy             | 0     | 1               | 2              | 3     | 4                |
| 5. It is hard for me to take a bath or shower by myself  | 0     | 1               | 2              | 3     | 4                |
| 6. It is hard for me to do chores around the house       | 0     | 1               | 2              | 3     | 4                |
| 7. I hurt or ache  | 0     | 1               | 2              | 3     | 4                |
| 8. I have low energy                                     | 0     | 1               |                | 3     | 4                |

| <b>ABOUT MY FEELINGS (problems with...)</b> | Never | Almost<br>Never | Some-<br>times | Often | Almost<br>Always |
|---|-------|-----------------|----------------|-------|------------------|
| 1. I feel afraid or scared                  | 0     |                 | 2              | 3     | 4                |
| 2. I feel sad or blue                       | 0     | 1               | 2              | 3     | 4                |
| 3. I feel angry                             | 0     | 1               | 2              | 3     | 4                |
| 4. I have trouble sleeping                  | 0     | 1               | 2              | 3     | 4                |
| 5. I worry about what will happen to me     | 0     | 1               | 2              | 3     | 4                |

| <b>HOW I GET ALONG WITH OTHERS (problems with...)</b> | Never | Almost<br>Never | Some-<br>times | Often | Almost<br>Always |
|---|-------|-----------------|----------------|-------|------------------|
| 1. I have trouble getting along with other kids       | 0     | 1               | 2              | 3     | 4                |
| 2. Other kids do not want to be my friend             | 0     | 1               | 2              | 3     | 4                |
| 3. Other kids tease me                                | 0     | 1               | 2              | 3     | 4                |
| 4. I cannot do things that other kids my age can do   | 0     | 1               | 2              | 3     | 4                |
| 5. It is hard to keep up when I play with other kids  | 0     | 1               | 2              | 3     | 4                |

| <b>ABOUT SCHOOL (problems with...)</b>           | Never | Almost<br>Never | Some-<br>times | Often | Almost<br>Always |
|--|-------|-----------------|----------------|-------|------------------|
| 1. It is hard to pay attention in class          | 0     | 1               | 2              | 3     | 4                |
| 2. I forget things                               | 0     | 1               | 2              | 3     | 4                |
| 3. I have trouble keeping up with my schoolwork  | 0     | 1               | 2              | 3     | 4                |
| 4. I miss school because of not feeling well     | 0     | 1               | 2              | 3     | 4                |
| 5. I miss school to go to the doctor or hospital | 0     | 1               | 2              | 3     | 4                |

|       |       |
|-------|-------|
| ID#   | _____ |
| Date: | _____ |

# PedsQL<sup>TM</sup>

## Pediatric Quality of Life Inventory

Version 4.0

PARENT REPORT for CHILDREN (ages 8-12)

### DIRECTIONS

On the following page is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling.

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.  
If you do not understand a question, please ask for help.

PedsQL 2

In the past **ONE month**, how much of a **problem** has your child had with ...

| <b>PHYSICAL FUNCTIONING (problems with...)</b>  | Never | Almost<br>Never | Some-<br>times | Often | Almost<br>Always |
|---|-------|-----------------|----------------|-------|------------------|
| 1. Walking more than one block                  | 0     | 1               | 2              | 3     | 4                |
| 2. Running                                      | 0     | 1               | 2              | 3     | 4                |
| 3. Participating in sports activity or exercise | 0     | 1               | 2              | 3     | 4                |
| 4. Lifting something heavy                      | 0     | 1               | 2              | 3     | 4                |
| 5. Taking a bath or shower by him or herself    | 0     | 1               | 2              | 3     | 4                |
| 6. Doing chores around the house                | 0     | 1               | 2              | 3     | 4                |
| 7. Having hurts or aches                        | 0     | 1               | 2              | 3     | 4                |
| 8. Low energy level                             | 0     | 1               | 2              | 3     | 4                |

| <b>EMOTIONAL FUNCTIONING (problems with...)</b>  | Never | Almost<br>Never | Some-<br>times | Often | Almost<br>Always |
|--|-------|-----------------|----------------|-------|------------------|
| 1. Feeling afraid or scared                      | 0     | 1               | 2              | 3     | 4                |
| 2. Feeling sad or blue                           | 0     | 1               | 2              | 3     | 4                |
| 3. Feeling angry                                 | 0     | 1               | 2              | 3     | 4                |
| 4. Trouble sleeping                              | 0     | 1               | 2              | 3     | 4                |
| 5. Worrying about what will happen to him or her | 0     | 1               | 2              | 3     | 4                |

| <b>SOCIAL FUNCTIONING (problems with...)</b>                       | Never | Almost<br>Never | Some-<br>times | Often | Almost<br>Always |
|--|-------|-----------------|----------------|-------|------------------|
| 1. Getting along with other children                               | 0     | 1               | 2              | 3     | 4                |
| 2. Other kids not wanting to be his or her friend                  | 0     | 1               | 2              | 3     | 4                |
| 3. Getting teased by other children                                | 0     | 1               | 2              | 3     | 4                |
| 4. Not able to do things that other children his or her age can do | 0     | 1               | 2              | 3     | 4                |
| 5. Keeping up when playing with other children                     | 0     | 1               | 2              | 3     | 4                |

| <b>SCHOOL FUNCTIONING (problems with...)</b>      | Never | Almost<br>Never | Some-<br>times | Often | Almost<br>Always |
|---|-------|-----------------|----------------|-------|------------------|
| 1. Paying attention in class                      | 0     | 1               | 2              | 3     | 4                |
| 2. Forgetting things                              | 0     | 1               | 2              | 3     | 4                |
| 3. Keeping up with schoolwork                     | 0     | 1               | 2              | 3     | 4                |
| 4. Missing school because of not feeling well     | 0     | 1               | 2              | 3     | 4                |
| 5. Missing school to go to the doctor or hospital | 0     | 1               | 2              | 3     | 4                |

Appendix 10: State Trait Anxiety Inventory for Children (STAI-C)

For use by malena penney only. Received from Mind Garden, Inc. on August 8, 2018



To Whom It May Concern,

The above-named person has made a license purchase from Mind Garden, Inc. and has permission to administer the following copyrighted instrument up to that quantity purchased:

**State-Trait Anxiety Inventory for Children Sample Items:**

I feel upset

I feel relaxed

I worry too much

I notice my heart beats fast

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